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Surgical site infection

development and evaluation of methods for improved outcome assessment

Surgical site infection: development and evaluation of methods for improved outcome assessment

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ABSTRACT

Surgical site infections (SSI) are common and can cause substantial patient morbidity and burden to health services. SSI outcome assessment is important for routine follow-up, research and audit but accurate assessment is challenging, particularly after hospital discharge. Existing tools for SSI assessment are limited. They are designed for healthcare professional completion in hospital, are complex to apply and do not identify SSI consistently. Patient-centred tools are lacking. This PhD set out to address the limitations of current methods for SSI assessment with two studies.

Study 1 developed and validated a new SSI outcome measure, suitable for patient and/or healthcare professional completion after the patient has left hospital. An analysis of existing SSI tools and stakeholder interviews were undertaken to ensure content validity. Cognitive interviews were conducted to pre-test the measure. Finally, a large field-testing study was undertaken. Findings demonstrated that the measure was acceptable, reliable and valid for SSI assessment post-discharge.

Study 2 developed and evaluated a method for remote wound assessment using patient-generated digital images. A review of wound-photography literature informed the development of photography instructions for patients. A process for patients to transmit images using their own mobile device was developed by adapting existing software. Pre-testing was undertaken with cognitive interviews and observations to study acceptability to patients. Evaluation of the method was performed with a further group of patients testing the method remotely. Findings demonstrated that the method was feasible, usable and acceptable, producing high quality images to supplement data from the SSI measure to identify SSI.

The complementary methods developed in this work provide novel contributions to SSI outcome assessment, particularly for use when patients have left hospital. Future work is directed towards implementation and evaluation of these methods in routine follow-up, research and audit to enhance SSI outcome assessment, thereby improving surgical practice and patient outcomes.

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Firstly, I would like to thank all the patients and healthcare professionals who gave their time to participate in this research, without which the studies would not have been possible.

I am deeply indebted to my supervisors, Dr Kerry Avery and Professor Jane Blazeby for their expert advice, guidance and consistent support throughout my PhD. Thank you for all your time, encouragement and for inspiring me to do this in the first place.

I would also like to acknowledge the support and assistance of the following people who helped make this work possible: Professor Barnaby Reeves for his guidance, support and dependable reasoning; Mr Thomas Pinkney and Professor Melanie Calvert for their expert advice and encouragement; Mr Thomas Milne and Dr Alexandra Nicholson for their assistance in interviewing participants for the development of the outcome measure; Dr Sara Brookes and Professor Chris Rogers for their statistical advice; Dr Katy Chalmers for her assistance with study administration during my maternity leave; Miss Natalie Blencowe, Mr Samir Pathak and Miss Mahim Qureshi for their clinical opinions and assessments of image quality; Ms Alison Horne for her expertise in REDCap software and help with designing the online survey; Miss Anni Skilton for her guidance and knowledge in medical photography and Mr Jonathan Rees and Miss Anne Pullyblank (Principle Investigators for the Selfi wound study) for their support and engagement with the work. Additional thanks go to everyone who contributed through patient and public involvement (PPI), to the members of the wider Bluebelle study team of which there are too many to mention, to the research teams and surgical trainees at

the participating centres and to the staff at the Bristol Clinical Trials and Evaluation Unit. Working as part of a multidisciplinary team has taught me so many valuable things that I will take with me for the rest of my career.

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AUTHOR'S DECLARATION

I declare that the work in this dissertation was carried out in accordance with the requirements of the University's Regulations and Code of Practice for Research Degree Programmes and that it has not been submitted for any other academic award. Except where indicated by specific reference in the text, the work is the candidate's own work. Work done in collaboration with, or with the assistance of, others, is indicated as such. Any views expressed in the dissertation are those of the author.

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LIST OF ABBREVIATIONS

App	Application
ASA	American Society of Anaesthesiologists
ASPESIS	Additional treatment, Serous discharge, Erythema, Purulent exudate, Separation of the deep tissues, Isolation of bacteria, duration of inpatient Stay
BRC	Biomedical Research Centre
BYOD	Bring Your Own Device
CDC	Centres for Disease Control and Prevention
CFA	Confirmatory Factor Analysis
CI	Chief Investigator
COMET	Core Outcome Measures in Effectiveness Trials
COS	Core Outcome Set
CTEU	Clinical Trials and Evaluation Unit
CTT	Classical Test Theory
DIP	Deep Incisional Primary
DIS	Deep Incisional Secondary
DRF	Doctoral Research Fellowship
EEA	European Economic Area
EFA	Exploratory Factor Analysis
EU	European Union
GI	Gastrointestinal

GIRFT	Getting It Right First Time
GP	General Practitioner
HCAI	Healthcare-Associated Infection
HCP	Healthcare Professional
HPA	Health Protection Agency
HTA	Health Technology Assessment
ID	Identification
IQR	Interquartile Range
ISO	International Organization for Standardization
IT	Information Technology
LMIC	Low- and Middle-Income Countries
MAMS	Multi-Arm, Multi-Stage
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
NINSS	Nosocomial Infection National Surveillance System
NPS	National Prevalence Survey
NRES	National Research Ethics Service
NWCSP	National Wound Care Strategy Programme
PDQ	Post-Discharge Questionnaire
PGHD	Patient-Generated Health Data
PhD	Doctor of Philosophy

PHE	Public Health England
PIL	Participant Information Leaflet
PPI	Patient and Public Involvement
PQ	Patient Questionnaire
PROM	Patient-Reported Outcome Measure
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
REDCap	Research Electronic Data Capture
RfPB	Research for Patient Benefit
ROC	Receiver Operating Characteristic
SD	Standard Deviation
SISG	Surgical Infection Study Group
SOP	Standard Operating Procedure
SSI	Surgical Site Infection
SSISS	Surgical Site Infection Surveillance Service
UK	United Kingdom
UROM	Universal-Reporter Outcome Measure
US	United States of America
WHQ	Wound Healing Questionnaire
WReN	Wounds Research Network

CONTRIBUTION STATEMENT

Study 1: Development and validation of a new outcome measure for SSI (Chapters 2 and 3). This study was embedded within the wider Bluebelle feasibility study: a two-year National Institute for Health Research (NIHR)-funded feasibility study to explore whether it was possible to conduct a large multicentre randomised trial to compare the effectiveness and cost-effectiveness of different types of wound dressings after elective surgery [1]. The author of this thesis co-led the development and validation of the SSI outcome measure sub-study, under supervision from Professor Jane Blazeby (Chief Investigator for the Bluebelle study and co-supervisor of this PhD) and Kerry Avery (co-supervisor of this PhD). Staff at the Bristol Clinical Trials and Evaluation Unit (CTEU) were responsible for the ethics application and management of the wider study, in which the SSI measure work was embedded. The author of this thesis contributed to the development of study documentation relevant to the SSI measure sub-study including the participant information leaflet (PIL) and case report forms.

The author of this thesis undertook all steps in the content analysis of existing SSI tools, which involved identifying potentially important content domains to include in the new outcome measure (Phase 1). Identification of potential patient participants to take part in interviews to identify content domains (Phase 1) was conducted by research nurses and surgical trainees at participating centres involved in the wider Bluebelle study. A qualitative researcher from the Bristol Medical School, Alexandra Nicholson (A.N.) conducted and analysed the interviews. The involvement of another researcher to conduct the interview component of this study (rather than the author of this thesis) was necessary to adhere to timelines for the wider Bluebelle study whilst the author of this thesis was on maternity leave.

Transcription of interviews was supported by a research secretary at the Bristol Medical School. The author of this thesis conducted the synthesis of findings from the content analysis of existing literature and interviews (Phase 1) and item formulation and design of the preliminary of the SSI measure (Phase 2), under supervision and with contributions from other members of the Bluebelle study team (Jane Blazeby; J.M.B., Barnaby Reeves; B.R.; Melanie Calvert; M.C. and Thomas Pinkney; T.P.). Identification of potential patient participants to pre-test the measure (Phase 3) was conducted by research nurses and surgical trainees at participating centres involved in the wider Bluebelle study. The author of this thesis conducted and analysed the cognitive interviews to pre-test the outcome measure (Phase 3), assisted by an academic foundation doctor (Thomas Milne; T.M.) as part of his academic training placement at the Bristol Medical School (for which the author of this thesis was co-supervisor). The author of this thesis led and managed the cohort field-testing study to validate the SSI measure (Phase 4). Identification of potential patient participants, recruitment and clinical data collection was conducted by research nurses and surgical trainees at participating centres involved in the wider Bluebelle study. A research associate (Katy Chalmers, K.C.) at the Bristol Medical School assisted with the final two months of the cohort study administration whilst the author of this thesis was on a second maternity leave. The Bluebelle pilot RCT, which contributed data to the validation of the SSI measure (Phase 4), was conducted by members of the wider Bluebelle study team and managed by the CTEU. The author of this thesis conducted all analyses for the validation of the SSI measure (Phase 4), with statistical guidance from Sara Brookes (S.B.) at the Bristol Medical School. The author of this thesis presented findings at Bluebelle study full team meetings throughout all phases of the study and comments and suggested were invited from members of the wider Bluebelle team.

Study 2: Development and evaluation of a method for remote wound assessment using patient-generated digital images (Chapters 4 and 5). The author of this thesis led and conducted all phases of this study with discussion and review with her supervisors throughout. She was responsible for developing the protocol, the ethics application, the development and design of all study documents including participant information leaflets and interview topic guides, set-up and initiation of participating centres and staff training, survey administration, data collection and analysis and the patient and public involvement (PPI). Design of the study database and process for participants to transmit wound images was supported by a data manger (Alison Horne, A.H.). Research nurses and surgeons from participating centres identified and approached potential patient participants for both phases of the study (Phases 1 and 2). The author of this thesis conducted and analysed all cognitive interviews with observation to pre-test the method (Phase 1). She co-ordinated and managed the study to test the method remotely (Phase 2). Assessment of image quality (Phase 2) was performed by three clinical academic surgeons (Natalie Blencowe; N.B., Samir Pathak; S.P. and Mahim Qureshi; M.Q.).

PUBLICATIONS ARISING FROM THIS RESEARCH

The following four papers have been published arising from research completed within this thesis. The PhD researcher's involvement in generating the publications is stated, signed by the first and final authors, where applicable.

1. **Macefield RC**, Reeves BC, Milne TK, Nicholson A, Blencowe NS, Calvert M, Avery KN, Messenger DE, Bamford R, Pinkney TD, Blazeby JM. Development of a single, practical measure of surgical site infection (SSI) for patient report or observer completion. *Journal of Infection Prevention* 2017;18:170-179, doi:10.1177/1757177416689724.

R Macefield co-ordinated and managed the SSI measure development study, performed the content analysis of existing SSI tools, designed the preliminary SSI measure and subsequent revisions, and conducted and analysed cognitive interviews to pre-test the measure. RM was lead author of this paper, wrote the first draft, all subsequent revisions and collated other author contributions to produce the final draft of the paper. This work was embedded within the Bluebelle feasibility study (Chief Investigator: Jane Blazeby). A copy of this paper is included in the Appendices.

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2. Bluebelle Study Group. Validation of the Bluebelle Wound Healing Questionnaire for assessment of surgical-site infection in closed primary wounds after hospital discharge. *British Journal of Surgery* 2019; 160:226-235. doi:10.1002/bjs.11008

R Macefield co-ordinated and managed the SSI measure validation study, contributed to participant recruitment, data collection and performed all analyses. RM was lead author of this paper, wrote the first draft, all subsequent revisions and collated other author contributions to produce the final draft of the paper. This work was embedded within the Bluebelle feasibility study (CI: Jane Blazeby). Work was published under an agreed group authorship to reflect the collaborative work of the wider Bluebelle study group. A copy of this paper is included in the Appendices.

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3. Macefield R, Brookes S, Blazeby J, Avery, K, Bluebelle Study Group. Development of a 'universal-reporter' outcome measure (UROM) for patient and healthcare professional completion: a mixed methods study demonstrating a novel concept for optimal questionnaire design. BMJ Open 2019;9:e029741. doi:10.1136/bmjopen-2019-029741

R Macefield was the lead author of this methodology paper describing the novel design of the SSI outcome measure. RM performed data collection, analysis and interpretation, wrote the first draft of the manuscript, all

subsequent revisions and collated other author contributions to produce the final draft of the paper. A copy of this paper is included in the Appendices.

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4. Reeves BC, Rooshenas L, Macefield RC, Woodward M, Welton NJ, Waterhouse BR, Torrance AD, Strong S, Siassakos D, Seligman W, Rogers CA, Rickard L, Pullyblank A, Pope C, Pinkney TD, Pathak S, Owais A, O'Callaghan J, O'Brien S, Nepogodiev D, Nadi K, Murkin CE, Munder T, Milne T, Messenger D, McMullan CM, Mathers JM, Mason M, Marshall M, Lovegrove R, Longman RJ, Lloyd J, Lim J, Lee K, Korwar V, Hughes D, Hill G, Harris R, Hamdan M, Brown HG, Gooberman-Hill R, Glasbey J, Fryer C, Ellis L, Elliott D, Dumville JC, Draycott T, Donovan JL, Cotton D, Coast J, Clout M, Calvert MJ, Byrne BE, Brown OD, Blencowe NS, Bera KD, Bennett J, Bamford R, Bakhbakhi D, Atif M, Ashton K, Armstrong E, Andronis L, Ananthavarathan P, Blazeby JM. Three wound-dressing strategies to reduce surgical site infection after abdominal surgery: the Bluebelle feasibility study and pilot RCT. Health Technology Assessment 2019;23(39):1-166. doi: 10.3310/hta23390.

R Macefield co-led (with J Blazeby; CI) the development and validation of the SSI outcome measure sub-studies embedded within Bluebelle feasibility study and co-led (with L Rooshenas) the PPI work for the wider study. RM drafted the relevant components of the manuscript reporting this work for the

Bluebelle study monograph for the NIHR Health Technology Assessment (HTA) journal and commented on the final draft of the paper.

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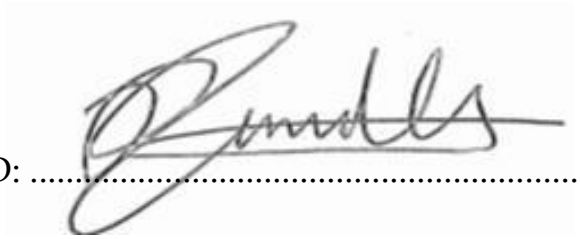
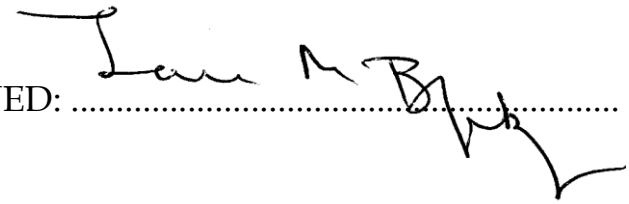
Additional publications with contributions from the author of this thesis relevant to the PhD research

The following eight papers relevant to the PhD research were also published with contributions from the author of this thesis during the course of the PhD work. Contributions are stated and signed by the first or last author of the papers, or Chief Investigator of the Bluebelle study (Jane Blazeby), where appropriate.

1. Dumville JC, Gray TA, Walter CJ, Sharp CA, Page T, **Macefield R**, Blencowe N, Milne TK, Reeves BC, Blazeby J. Dressings for the prevention of surgical site infection. Cochrane Database of Systematic Reviews 2016;12:CD003091. doi:10.1002/14651858.CD003091.pub4.

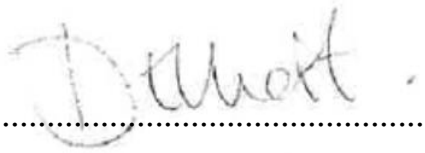
R Macefield contributed to the update of this review, checked the quality of data extraction, undertook and checked quality assessment, and checked quality of statistical analysis, performed part of the editing, made an intellectual contribution to the review update, and approved the final version of the review update prior to submission.

SIGNED:  DATE: 16/03/2020

SIGNED:  DATE: 12/03/2020

2. Elliott D, Bluebelle Study Group. Developing outcome measures assessing wound management and patient experience: A mixed methods study. BMJ Open BMJ Open. 2017;7(11):e016155. doi: 10.1136/bmjopen-2017-016155

R Macefield conducted literature reviews, contributed to the design of the new outcome measures and commented on earlier and final drafts of the manuscript.

SIGNED:  DATE: 16/03/2020

3. Blazeby J, Bluebelle Study Group. The Bluebelle pilot randomised controlled trial of three wound dressing strategies to reduce surgical site infection in primary surgical wounds. BMJ Open 2020;10(1):e030615. doi: 10.1136/bmjopen-2019-030615.

4. McMullan C, Blazeby J, Donovan JL, Rooshenas L, Elliott D, Mathers J, Bluebelle Study Group. Dressing use issues in primary abdominal wounds: a qualitative study of health staff and patient views. British Journal of Nursing 2019;28(20):S10-S18. doi: 10.12968/bjon.2019.28.20.S10.

5. Bluebelle Study Group, Reeves BC, Andronis L, Blazeby JM, Blencowe NS, Calvert M, Coast J, Draycott T, Donovan JL, Gooberman-Hill R, Longman RJ, Magill L, Mathers JM, Pinkney TD, Rogers CA, Rooshenas L, Torrance A, Welton NJ, Woodward M, Ashton K, Bera KD, Clayton GL, Culliford LA, Dumville JC, Elliott D, Ellis L, Gould-Brown H, **Macefield RC**, McMullan C, Pope C, Siassakos D, Strong S, Talbot H. A mixed-methods feasibility and external pilot study to inform a large pragmatic randomised controlled trial of the effects of surgical wound dressing

strategies on surgical site infections (Bluebelle Phase B): study protocol for a randomised controlled trial. Trials 2017;18(1):401. doi: 10.1186/s13063-017-2102-5.

6. Severn and Peninsula Audit and Research Collaborative for Surgeons (SPARCS) and West Midlands Research Collaborative (WMRC) on behalf of the Bluebelle Study Group. Feasibility work to inform the design of a randomized clinical trial of wound dressings in elective and unplanned abdominal surgery. British Journal of Surgery 2016;103(12):1738-1744. doi: 10.1002/bjs.10274.

7. Rooshenas L, Bluebelle Study Group, Severn and Peninsula Audit and Research Collaborative for Surgeons, West Midlands Research Collaborative. Bluebelle study (phase A): a mixed-methods feasibility study to inform an RCT of surgical wound dressing strategies. BMJ Open 2016;6(9):e012635. doi: 10.1136/bmjopen-2016-012635.

8. Severn and Peninsula Audit and Research Collaborative for Surgeons (SPARCS) and West Midlands Research Collaborative (WMRC) on behalf of the Bluebelle Study Group. Feasibility work to inform the design of a randomized clinical trial of wound dressings in elective and unplanned abdominal surgery. British Journal of Surgery 2016;103(12):1738-1744. doi: 10.1002/bjs.10274.

R Macefield was a member of the Bluebelle Study Group and commented on earlier and/or the final drafts of the manuscript for all the above publications.

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CHAPTER 1. SURGICAL SITE INFECTION AND METHODS OF ASSESSMENT

"Decomposition or putrefaction has long been known to be a source of great mischief in surgery"

Joseph Lister, 1867

1.1. Introduction

Infection of the wound after surgery, clinically known as surgical site infection (SSI), has been a problem throughout the history of surgery. In the early nineteenth century, wound infection was common and uncontrollable, literally causing decomposition, decay and rotting in the body. Mercifully, surgical practice has changed dramatically since the Victorian era when surgeon Joseph Lister pioneered wound infection control [2]. The significance of SSI and the importance of adopting measures to reduce it are now widely recognised. Accurate and reliable methods to assess and monitor SSI for routine surgical follow-up, research and audit, however, is an issue that continues to challenge surgical practice today.

This introductory chapter serves three main purposes. First, it describes surgical site infections: their history, prevalence and why they are a problem for patients and the health service. Second, the chapter describes how SSI is defined and the existing tools available for SSI assessment and diagnosis. Limitations of these tools are explained. Next, the concept of measurement theory is introduced, and the use of questionnaires and grading scales for measuring SSI. Finally, the chapter introduces the concept of using digital images as a method for remote wound assessment. It describes how advances in mobile technology provide a cutting-edge method for obtaining images directly from patients. The chapter concludes with a summary of these topics, bringing them together to outline the aims and objectives of this thesis.

1.2. Surgical site infection: an overview

1.2.1. What is a surgical site infection?

A surgical site infection (SSI) is an infection that occurs in the part of the body where surgery took place [3]. It can be an infection in the layers of skin, or it can involve the underlying tissues or organs. An SSI occurs when bacteria multiply within a wound and produce toxins, triggering the body's immune response. Consequences can range from minor symptoms of inflammation, such as swelling and pain, to systemic problems that affect the whole body, such as overwhelming sepsis. Sepsis occurs when the immune system overreacts and starts to damage the body's own tissues and organ. It is life-threatening and may result in death. Most SSIs are caused by contamination of micro-organisms from the person's own body during surgery. Less commonly, SSIs may be caused by contamination from an external source [4].

1.2.2. The history of SSI

Surgical site infections and the dangers and risks they pose have been notorious throughout surgical history. Until the 1840s before the era of antiseptics, the threat of contracting an infection in the wound after surgery was regarded as more dangerous than the primary surgery itself. The risks of surgery itself were already well recognised, and greatly limited the type of procedures that were attempted, with many surgeons restricting their scope to treatment of external problems such as minor skin conditions and superficial wounds, or only the most essential amputations [5]. In conditions where hospitals were notoriously known as 'death houses', many patients who survived surgery, however, succumbed to infections and many died as a result [5]. In London in the mid-1850s, approximately 50% people undergoing surgery for an amputation died, with most of those deaths attributed to SSI [6].

Several revolutionary medical advances took place in the Victorian era that led to the understanding of how infections are contracted, and that contamination is caused by germs. In the 1860s, Lister's discovery of the benefits of using antiseptics for sterilising surgical practice was game-changing, substantially reducing rates of SSI [2,5]. Clean operating theatres, sterile instruments and basic procedures like hand washing, for example, are now standard practice. Evidence from randomised controlled trials (RCTs) has further extended this knowledge, and many more effective interventions to reduce SSI are known. Many SSIs are avoidable, and guidance is available for their prevention and treatment in the UK and worldwide [4,7]. Current UK National Institute for Health and Care Excellence (NICE) guidance, for example, includes recommendations for SSI prevention in pre-operative,

intraoperative and postoperative surgical phases [8]. Examples include advising patients to bath or shower before surgery, using antiseptic skin preparations during surgery and using sterile saline to clean wounds after surgery. Ongoing research seeks to find further interventions to prevent SSI. The use of antimicrobial-impregnated drapes, sutures and specialist wound dressings, for example, are some of the interventions currently being evaluated [9]. Despite preventative advances, SSIs still occur in surgical practice. They continue to pose a significant threat and represent a global healthcare problem in surgery today, affecting millions of people worldwide [7].

1.2.3. The effect of SSI on the patient and the health service

The severity of SSI can range from minor, non-problematic infections to more major, serious infections. In today's surgical practice, most SSIs are superficial. They may involve minor symptoms such as redness or swelling around the wound, or some leaking of fluid. These symptoms can mostly be resolved with simple treatment of oral antibiotic therapy. The control of SSIs has undoubtedly been transformed since the discovery of antibiotics. There is a tendency, however, to over-treat, meaning that SSIs may contribute to the spread of antibiotic resistance [7]. Other SSIs can, however, have more serious effects. Patients may require admission to hospital for intravenous antibiotics. Serious infections can cause abscesses which may require treatment in theatre, for example, re-opening the wound to drain fluid or pus. Significant costs to the health services may be endured, requiring hospital readmissions and extended hospital stays [10]. When a serious SSI has occurred, there is often prolonged wound healing. This can have a subsequent detrimental impact on

patients' quality of life and ability to return to work. The most severe SSIs can still be life-threatening today.

1.2.4. The prevalence of SSI

SSIs are one of most common adverse events to occur after surgery [11]. Surgery plays a major role in treating patients in today's society, with approximately eight million surgical procedures estimated to be performed in the UK each year [12]. It is estimated that at least one in every 20 (5%) patients undergoing a surgical procedure will develop an SSI [4]. The number of people at risk of SSI is therefore high [13]. After pneumonia and urinary tract infection, SSIs are the third most common healthcare-associated infection (HCAI) in Europe, compromising 18.4% of all HCAI infections in 2016-2017 [14,15]. Around 800,000 cases of SSI per year have been estimated in the European Union and European Economic Area (EU/EEA), with an estimated 16,049 resulting in death [16].

Incidence of SSI varies depending on many factors, such as the part of the body in which the surgery is performed, whether surgery is elective or unplanned and patient risk factors. The risk of contracting an SSI are greater, for example, if the surgery is an emergency procedure or in an area susceptible to contamination, such as the bowel [17]. Longer or more complex surgeries also carry an increased risk. Patients who suffer from co-morbidities are more likely to experience an SSI. Other patient risk factors include diabetes, obesity or if the patient is a smoker [17].

1.2.5. Timing of SSI appearance

In today's healthcare systems in developed countries there is a drive for shorter hospital stays. The changing nature of care, including advances in minimally invasive surgical technologies and enhanced recovery programmes, means that the proportion of day case surgeries has increased. Consequently, signs and symptoms of SSI often become apparent after the patient has left hospital; a situation that is becoming increasingly more common as hospitals stays become shorter. A systematic review of studies published over the last 20 years found that, of 140,000 infections diagnosed, most (60.1%, range 13.5% to 94.8%) occurred after hospital discharge [18]. The appearance of SSI after patients have left hospital presents several challenges for SSI assessment and the accurate measurement of SSI rates. This issue is fundamental to the aims of this thesis and will be described in more detail later in this chapter. First, it is important to describe why it is essential to accurately assess SSI as an outcome and measure and monitor SSI rates.

1.2.6. The importance of SSI outcome assessment

Assessment of SSI is crucial for routine surgical follow-up, research and audit. After surgery, monitoring of the wound for SSI is important so that early detection of problems can be treated and prevent further consequences [8]. In research and clinical trials, accurate SSI outcome assessment is essential in order to effectively evaluate interventions for their prevention or treatment [19,20]. Surveillance of SSI in-hospital statistics is necessary for benchmarking, that is, the sharing and comparing of practice across different hospitals, with the aim to identify best practice and to develop plans to remedy poor practice [21]. Measuring and monitoring rates of SSI is also required for priority

setting in the healthcare service; that is, deciding which interventions to carry out with the aim to reduce SSI.

In the UK, there are several current initiatives in place to capture information on SSI rates. Public Health England (PHE) has a surgical site infection surveillance service (SSISS) which aims to help hospitals in England record incidents of SSIs and use the results to review or change practice as necessary [22]. The programme started in 2004 under the former UK government-funded Health Protection Agency (HPA). Surveillance of SSI is mandatory in four types of orthopaedic surgery (hip replacements, knee replacements, repair of neck of femur and reduction of long bone fracture) under the PHE scheme. Surveillance is voluntary in 13 other surgical categories (for example, breast and cardiac surgery). Since 2016, the UK also has the Getting it Right First Time (GIRFT) programme; an initiative funded by the Department of Health that aims to improve the quality of care within the National Health Service (NHS) by reducing variations in the way that services are delivered and encourage the sharing of best practice [23]. A major project and cross-cutting theme in the programme is an SSI audit; set up to measure and review SSI rates and review current practice in SSI prevention [24]. The UK also has the National Wound Care Strategy Programme (NWCSP), commissioned by NHS England and NHS Improvement in 2018 [25]. The aim of the programme is to improve the quality of wound care across England. Surgical wounds are one of three types of wound under focus of the programme (others being pressure wounds and lower limb wounds) with improved monitoring and measurement of SSI high on the agenda. These initiatives are, however, faced with challenging and problematic accurate SSI assessment. These issues will now be described.

1.2.7. Problems with SSI assessment

Accurate SSI assessment is challenging, hindered in part by the fact that patients are increasingly discharged soon after their surgery. This means that methods for detecting SSI post-discharge are required to obtain accurate data of SSI incidence. Robust methods for post-discharge follow-up, for example, telephone calls and face-to-face assessments are, however, resource-intensive and costly [26]. As a result of different methods for collecting SSI data, wide discrepancies in reported rates of SSI exist. For example, data from SSI surveillance in NHS hospitals in England report an incidence of inpatient and readmission SSI in large bowel surgery of 8.7% [27]. This does not, however, include cases of SSI that occur post-discharge that are treated in the community. It is likely, therefore, that it considerably underestimates the true incidence of SSI. In contrast, estimates of SSI rates after elective colorectal surgery in Spain, when surveillance included post-discharge SSI, have been reported to be as high as 20.7% [28]. Data from trials have reported higher rates still, with SSI incidence in patients undergoing laparotomy (incisions into the abdomen) reaching 25.4% [29]. This variation in reported SSI rates can, in part, be attributed to the methods used to detect SSI and collect information for surveillance programmes compared to research studies. The availability of resources such as staff, for example, will impact on the robustness of data collection and the procedures and methodology used for follow-up. It has been argued the most reliable SSI rates are provided by control arms of RCTs, where a more motivated and dedicated approach to patient follow-up enables more accurate detection of SSI after hospital discharge. Problems resulting from limitations of existing methods used for assessing and monitoring SSI, are central to the aims of this thesis.

In summary, challenges are faced with accurately determining whether patients have experienced an SSI. A major challenge is that many SSIs occur after the patient had left hospital and robust methods for post-discharge surveillance are resource intensive and costly. A further and related challenge is that the existing tools that are used to diagnosis and measure SSI have limitations. The following paragraphs introduces this issue, describing the currently available tools and their shortcomings.

1.3. Diagnosing and measuring SSI

Accurate and reliable methods for detecting and diagnosing SSI are crucial in tackling the big problem that SSIs continue to be in global health today. As described at the start of this chapter, SSI is caused by bacteria multiplying within a wound and causing a reaction [3]. Diagnosing SSI, however, is complex, which causes problems for accurate assessment of SSI rates important for research, benchmarking and priority setting, as described. Defining or diagnosing SSI is complex because it is not a single entity that can be measured directly, like height or weight [30]. Instead, it is diagnosed or defined from multiple characteristics, including clinical signs and symptoms. Some of these signs and symptoms are directly observable (such as swelling, for example), while others are not (such as pain). Diagnosis of SSI may also include microbiological evidence of bacterial infection. The combination of signs and symptoms that are commonly used to define an SSI are described below, followed by a summary of existing tools that are currently available for measuring SSI.

1.3.1. Defining SSI

What defines surgical site infection?

There is no single agreed definition of SSI. Various definitions are available and used in practice. A methodologically robust systematic review of SSI measurement and monitoring conducted by Bruce et al. in 2001 [31] identified the most commonly used definition by far was that published by the U.S. Centres for Disease Control and Prevention (CDC) [32,33]. This remains to be the most used definition, demonstrated, for example, in a Cochrane overview of systematic reviews of interventions for preventing SSI during surgery [19]. The CDC categorises three types of SSI: superficial, deep and organ/space. The different types are determined by on a combination of criteria that must be met, including signs, symptoms and microbiology. Criteria include, for example, localised pain, swelling, purulent exudate (pus), presence of an abscess, wound dehiscence or organisms identified from microbiological tests. The combination of criteria required to meet the different types of SSI are displayed in Box 1.

The CDC definition was first published in 1992 and was updated in 2008 to distinguish between deep incisional primary (DIP) and deep incisional secondary (DIS) SSIs [32]. Despite being widely used in surveillance programmes and research [34,35], the CDC definition has been criticised as being complex to use and difficult to apply in practice [36,37]. For example, a study demonstrating poor reliability between surgeons' diagnosing SSI using the CDC criteria questioned whether differences were due to subjectivity and interpretation of the CDC criteria or true differences in clinical interpretation [37,38]. With this in mind, the UK Nosocomial Infection National Surveillance System (NINSS) (now superseded by the PHE SSISS) developed a modified

version of the CDC diagnostic criteria for SSI, with the aim to improve its objectivity and practicality for use in a hospital setting [39]. For example, the criterion of "diagnosis of a superficial incisional SSI by the surgeon, attending physician or other designee" was excluded due to its vagueness and subjectivity as a criterion for diagnosis. Despite this, the combination of criteria that make up the definition remains complex to use. There is still considerable subjectivity because assessment allows for only dichotomous yes/no judgement of whether criterion for signs and symptoms have been met, as detailed below.

Box 1. Centres for Disease Control and Prevention (CDC) definitions and criteria for SSI (2014) [40]

Superficial Incisional Infection

SSI involving only the skin or subcutaneous tissue of the incision AND occurs within 30 days of surgery AND meets at least **one** of the following criteria:

1. Purulent drainage from superficial incision

2. Organisms isolated from an aseptically-obtained culture from the superficial incision or subcutaneous tissue

3. Incision deliberately opened to manage infection and is culture positive or not cultured **and** at least 1 symptom of: *pain/tenderness, localised swelling, redness or heat*

4. Clinicians' diagnosis of superficial SSI

Note: Stitch abscesses (minimal inflammation/discharge at suture point) do not classify as SSI

Deep Incisional Infection

SSI involving the deep tissues (i.e. fascial & muscle layers) AND occurs within 30 days of surgery AND meets at least one of the following criteria:

1. Purulent drainage from deep incision (not organ space)

2. Deep incision dehisces or is deliberately opened and is culture positive or not cultured and patient has at least 1 symptom of: fever (<38^{o}C) or localised pain/tenderness

3. Abscess or other evidence of infection involving the deep incision that is detected on re-operation / histopathology / radiology

Note: An infection involving both superficial and deep incisional = deep incisional

Organ/space Infection

SSI involving any part of the body deeper that the fascial/muscle layers that is opened or manipulated during the surgical procedure AND occurs within 30 days of surgery AND meets at least **one** of the following criteria:

1. Purulent drainage from a drain that is placed into the into organ/space (e.g. closed suction drainage system, open drain, T-tube drain, CT guided drainage)

2. Organisms isolated from an aseptically-obtained culture of fluid or tissue in the organ/space

3. Abscess or other evidence of infection involving the organ/space that is detected on *re-operation / histopathology / radiology*

Note: If infection drains through incision = deep incisional

The Bruce et al. 2001 systematic review identified other standard definitions for SSI [31]. These, however, are less detailed and comprehensive than the CDC definition and are not widely used in current practice. One example is the definition developed by Glenister and colleagues [41]. The definition specifies that a wound infection must have purulent discharge, with major infection present when the wound is also broken down, gaping or completely dehisced, or there is evidence of septicaemia, spreading cellulitis or lymphangitis. Another example is the definition published by the UK Surgical Infection Study Group (SISG) in the early 1990s [42]. The proposed definition, intended to be suitable for bedside diagnosis, includes purulent discharge in, or exuding from, the wound, or a painful, spreading erythema indicative of cellulitis. It states that infection should be considered to be present when there is fever, tenderness, oedema and an extending margin of the erythema [42]. Also in the early 1990s, the second UK National Prevalence Survey (NPS) published a definition almost identical to that from the SISG with the exception not defining SSI by the timeframe in which it presents [43].

Although these definitions for SSI vary in the number and combination of indicators used to define SSI, there are many similarities and substantial overlap in the indicators that they describe. Purulent discharge, redness and swelling, for example, are shared features of all definitions [11,31]. A criticism of all these definitions used to diagnose SSI, however, is that they are based on a simple, dichotomous clinician's judgement of whether a sign or symptom is present or absent. This judgement can be highly subjective and can vary depending on the person assessing the wound. In addition, none of these definitions provide an opportunity to take the severity of the individual signs or symptom into account. This issue will be revisited later in this chapter.

1.3.2. Existing tools for diagnosing and measuring SSI

Several tools have been developed to facilitate SSI diagnosis and assessment. The review by Bruce et al. (2001) and a subsequent 2006 systematic review of methods for identifying SSI after hospital discharge [31,44], for example, identified SSI criteria checklists, grading scales and questionnaires for patients. These tools will now be described, and their strengths and limitations compared. A scoping search conducted for the purpose of this thesis verified that no new validated tools had been developed since the Bruce et al. 2001 review was undertaken.

Checklists of SSI criteria

The most commonly used tools in SSI surveillance and research are based on the CDC criteria and definition for SSI [31]. In practice, these are typically 'checklists' of criteria, that is, written lists of the individual diagnostic criteria that contribute to the definition of SSI. For example, the UK PHE SSISS surveillance programme uses a checklist of SSI criteria based on the CDC definition in their surveillance data collection sheets. A list of the diagnostic criteria from the CDC definition, for example "localised swelling" and "purulent drainage", are listed in alphabetical order in the data collection forms, with an accompanying 'tick box' next to each criterion. If the wound displays a sign or symptom that is included in the list, the person assessing the wound can mark on the checklist that the sign or symptom is present by ticking the adjacent box. Responses can then be used to determine whether the combination of criteria that determines SSI in the CDC definition has been met.

Simple checklists of criteria based on SSI definitions may be helpful in practice to record information to aid diagnosis and categorise SSI, but they have their limitations. As mentioned in the previous section, judgements are limited to a binary "yes" or "no" opinion. This judgement is subjective, meaning responses can vary between individuals who are assessing the wounds and consequently can lead to inconsistent diagnoses between assessors. There may be variation in the interpretation of, for example, what purulent discharge is. There may also be variation in the judgement of what amount of discharge would qualify as meeting that criterion because only a 'yes' or 'no' response is allowed. This subjectivity in judgement can mean that diagnoses may be inconsistent when different people assess the wound, and it can also mean diagnoses may vary when the same individual assesses the wound. This has problems for SSI measurement and monitoring as it may lead to variability in SSI rates, by calling into question the accuracy and reliability of the data.

Fundamentally, checklists of SSI criteria don't 'measure' SSI because they do not quantify the frequency or severity of a contributing sign or symptom; instead, they simply record whether a sign or symptom is present or absent. These observations are then combined to inform a decision as to whether an SSI is present or not (that is, a binary outcome). The following paragraphs introduce the idea that SSIs can, instead, be more quantitatively measured using a numerical scale. First, the theory of how health, and health conditions, may be assessed (measured) is introduced before describing how the theory may be applied to the assessment of wounds for SSI.

Measurement theory

Since the mid-1900s, medicine has benefitted from the development and application of what is commonly referred to as measurement theory, and accompanying statistical models, to assess unobservable health conditions [30]. Popularised from the fields of psychology and education, a measurement theory approach is based on the philosophy that underlying, unobservable traits and characteristics, for example, intelligence, can be assessed indirectly from observable 'measurable' indictors, such as reading and language ability [45]. Translating this to medicine, measurement theory implies that many unobservable health conditions are reflected by observable characteristics that are related to and represent that underlying health condition. To apply this in practice, it is first necessary to define the health condition. The question "What is the 'concept' of the health condition?" needs to be considered. Next, the application of measurement theory requires the selection of indicators (observable characteristics) that represent that concept. Finally, numerical scores are assigned to these indicators so that the health condition can be 'measured' [30,46].

Health measurement instruments

In comparison to checklists of SSI criteria, health measurement instruments are tools that help us to measure, rather than simply record, the observable characteristics or indicators of health or a health condition. They vary in terms of where they lie on the subjective-objective spectrum. Instruments that measure biological and physiological indicators, such as blood pressure monitors and laboratory tests, for example lie at the more objective end of the measurement spectrum. They allow measurement with minimal or no need for personal judgement and are less influenced by the person taking that

measurement [46]. Although these appear objective, they are subject to measurement error as for any tool [47]. At the other end of the spectrum lie subjective measurement instruments, which are influenced by the person performing the measurement, or the actual person being measured themselves. Examples include measurement of patients' symptoms; feelings that are directly experienced by the patient. Other examples include measurement of clinical signs; characteristics that can be observed by the clinician examining that patient [46]. For the context of this thesis, only tools that can be completed by a patient or clinician will be examined. It will not include tools such as laboratory tests.

Historically, assessment of subjective health indicators was limited to conversations between the patient and the clinician in face-to-face assessments. Since the 1930s the assessment of subjective health indicators has advanced. Much has been accomplished in methodology for developing tools to assess subjective states through the use of questionnaires and rating scales [30]. Accurate measurement, however, requires carefully developed and validated tools to ensure that data are reliable and valid. The properties required for a measurement tool to be considered high quality will be detailed in the following chapter. Questionnaires and rating scales typically comprise a list of 'items', often written as questions, with response options that can be answered by the person completing the tool [46]. Items are developed to collect information on a specific 'indicator' of the health issue of interest, with responses that can be scored in a meaningful way. If several items are scored in a combined way they are referred to as a scale [48].

Questionnaires and rating scales offer several advantages for measuring health. They can be developed for healthcare professionals to complete. They can also be developed to collect data directly from patients themselves. Patient-completed tools are important for measuring patients' experiences and symptoms. They are referred to as patient-reported outcome measures (PROMs) [49]. Patient-completed tools also have advantages for remote data collection when the patient can complete and return data by post or using electronic data collection systems. There is also a new form of tool that has been developed although not yet validated called a universal-reporter outcome measure (UROM). This is a single tool that can be completed by a patient and/or a professional, when applicable [50].

Following this brief description of measurement theory and health measurement instruments, it will now be explained how this relates to measuring SSI.

SSI grading scales

A grading scale is a name that has been given to a type of measurement instrument that can be used to describe the severity of a condition. While there are no SSI grading scales for patient completion, clinician-completed SSI grading scales exist. Unlike the tools based on the CDC criteria and definition for SSI which allow for a binary (yes/no) outcome, a grading scale allows for a measurement of SSI along a spectrum of severity. The most commonly used grading scale is the ASEPSIS grading scale [51]. The ASEPSIS grading scale was developed in the early 1980s as a 'wound scoring method' for use in a randomised controlled trial of antibiotic prophylaxis in cardiac surgery. It consists of a list of observable wound characteristics or features that can be

assessed by the clinician for each wound. Observable characteristics listed in the tool include serous exudate, purulent exudate, erythema and separation of deep tissue. Responders are asked to indicate the proportion of the wound affected. Further non-subjective criteria include, for example, treatment with antibiotics and wound debridement. Responses are assigned numerical scores (termed in the tool as 'points') with additional points for the objective criteria (Box 2). Wounds are assessed daily, and scores are summated.

Box 2. ASEPSIS grading scale (Additional treatment, the presence of Serous discharge, Erythema, Purulent exudate, and Separation of the deep tissues, the Isolation of bacteria, and the duration of inpatient Stay)

Points scale for daily wound inspection						
	Proportion of the wound affected (%)					
Wound characteristic	**0**	**<20**	**20-39**	**40-59**	**60-79**	**>80**
Serous exudate	0	1	2	3	4	5
Erythema	0	1	2	3	4	5
Purulent exudate	0	2	4	6	8	10
Separation of deep tissues	0	2	4	6	8	10

The wound score	
Criterion	**Points**
Additional treatment	
Antibiotics	10
Drainage of pus under local anaesthesia	5
Debridement of wound (general anaesthesia)	10
*Serous discharge**	daily 0-5
*Erythema**	daily 0-5
*Purulent exudate**	daily 0-10
*Separation of deep tissues**	daily 0-10
Isolation of bacteria	10
Stay as inpatient prolonged over 14 days.	5

** Given score only on 5 of first 7 postoperative days*
Category of infection: total score 0-10=satisfactory healing; 11-20=disturbance of healing; 21-30=minor wound infection; 31-40=moderate wound infection; >40=severe wound infection

The ASEPSIS grading scale has been recognised as less subjective than other methods for assessing wounds for infection such as the CDC criteria described above [52]. This is because attempts to quantify the proportion of the wound affected can be considered rather than a binary yes/no judgement as required by the CDC criteria checklists. The ASEPSIS scale also allows for a

grading of the severity of the problem. The ASEPSIS scale has shown good reliability between assessors and is comparable and reproducible [11,36,53]. Despite being recognised as an important development in SSI measurement at the time of its conception, the ASEPSIS grading scale has limitations for SSI measurement and is less widely used than the CDC definition [52]. It was developed for use in-hospital by healthcare professionals and requires a daily assessment of the wound. This can be timely and resource intensive. Applying an estimate of the proportion of the wound can also be difficult in practice. Studies have reported that the score is cumbersome to collect and may need to be simplified to be clinically viable [37]. In addition, head-to-head comparisons of SSI diagnoses when both the CDC and ASEPSIS tools have been used have found inconsistencies in numbers of SSIs diagnosed [36,37,54,55]. These limitations of the ASEPSIS grading scale are summarised in Box 3.

Other grading scales for SSI exist [31]. They have not, however, been widely adopted, with little evidence of their use outside of the studies in which they were developed [31]. These grading scales were primarily developed for use within individual studies, were not developed with robust methodology and have not been validated. The exception is the Southampton Wound Assessment scale, which was the only other grading scale identified in the review that had been assigned a specific name [56]. The Southampton scale was developed in 1992 for detecting wound complications after hernia surgery. The scale comprises five grades determined from assessments of bruising or haematoma, erythema and other signs of inflammation, clear or haemoserous discharge, pus and 'deep or severe wound infection'. The scale has been validated and used in subsequent studies outside of hernia surgery but, like ASEPSIS, has been criticised as labour-intensive and time-consuming to complete [53].

Box 3. Weaknesses and limitations of the CDC definition and ASEPSIS grading scale - the most commonly used SSI definition and grading scale identified in the Bruce et al. 2001 review

Definition / grading scale	**Weakness/ limitation**
CDC	• Subjective interpretation of criteria • Binary yes / no judgements; no grading of severity • Complex combination of criteria to define SSI; difficult to use in practice • Poor reliability between assessors
ASEPSIS grading scale	• Developed for use in-hospital • Time consuming to complete • Resource intensive; requires daily assessment of the wound • Requires estimation of the proportion of the wound affected which can be difficult in practice • Complex scoring system

SSI questionnaires

Health measurement instruments can be designed as questionnaires for patient and/or clinician completion, as previously described. There are, however, no existing questionnaires that have been developed and validated specifically as a measurement instrument for SSI. This was evident from the systematic reviews conducted by Bruce et al. in 2001 and Petherick et al. in 2006 [31,44]. The reviews identified some questionnaires designed to supplement other data collected from hospital records or data reported by clinicians. Examples include the PHE SSISS Post-Discharge Questionnaire (PDQ) (Appendix 4). The questionnaire was designed for patients to complete 30 days following surgery. It includes items to collect information on possible SSI signs and symptoms (such as wound redness and pain), antibiotic prescription and hospital admissions for SSI, and is used to supplement surveillance data as part of the SSISS programme. An ASEPSIS-associated patient questionnaire also exists and has been used in trials to collect information on SSI signs and symptoms from patients after leaving hospital [57,58] (Appendix 5). Although designed for patient completion, neither the PHE nor the ASEPSIS-associated patient questionnaires involved patients in their development, which is now recognised as a key quality indicator of questionnaire development and validation [45]. They have also not been formally validated or tested to ensure the language is appropriate and understood by patients. Importantly, they were not developed for use as a standalone tool for SSI measurement or diagnosis. Instead they were designed to collect supplementary information for surveillance and trial purposes.

In summary, problems with SSI assessment remain. The current, most commonly used tools for diagnosing and measuring SSI are sub-optimal, as detailed in Box 3. Importantly, the CDC definition and the ASEPSIS grading scale were designed for completion by a healthcare professional in a face-to-face assessment with the patient. They are suitable for use if the patient is still in hospital. After the patient has been discharged, however, assessment of the wound using these tools becomes more complicated. Bringing the patient back to hospital for a face-to-face assessment may be logistically or practically challenging for patients. Being seen in the community for a face-to-face assessment, for example, by a healthcare professional visiting the patient at home, is resource intensive and expensive. Use of these tools do not allow for remote assessment and have implications, therefore, for trials and routine surveillance. An SSI outcome measure suitable for patient completion could allow for remote assessment, however, no such tool exists.

Evidence suggests there is a need for better measures and methods for SSI assessment after hospital discharge, the time when SSI signs and symptoms most often become apparent. A new tool – a measurement instrument that is reliable, valid and suitable for use both in-hospital and after the patient has left hospital - is needed. A tool that can be completed by healthcare professionals and by patients is desired so that it can be used in either or both of these settings. The following paragraphs will now turn to another method with potential to address the challenge of assessing wounds after the patient has left hospital. The use of technology and digital wound images will be described and how this may benefit SSI outcome assessment after the patient has left hospital.

1.4. The use of digital photography for assessing wounds

There is a growing body of evidence that a photographic image of the wound is a valuable tool for monitoring and aiding the diagnosis of various wound complications [59-61]. This has obvious advantages for remote wound assessment, when the specialist is unable to see the patient face-to-face or when there is a need for regular monitoring of how the wound is healing. Being able to review an image of the wound has advantages when clinic visits are difficult for logistical or financial reasons. Whilst other information is also required for identifying and diagnosing SSI, such as patient reports of symptoms, for example, images may be used together with such data providing a valuable method for remote post-discharge follow-up and SSI outcome assessment [62].

1.4.1. Existing use of wound images in research and routine practice

The use of digital images in healthcare is well established. Reviewing images is an integral part of telemedicine, defined as "the use of electronic information and communications technologies to provide and support health care when distance separates participants"[63]. In dermatology, for example, remote monitoring of patients' skincare conditions using photographic images has been used for decades [64,65]. Specifically in the field of wound care, telemedicine and digital images have been used as a method for monitoring of chronic wounds, such as leg ulcers [66]. In the context of clinical trials, the use of anonymised digital images can enable blinded

outcome assessment to take place. This can avoid any systematic difference between groups in how the outcomes are assessed (that is, detection bias) because knowledge of the intervention group is unknown [67]. An example is the WOLLF trial; a randomised controlled trial that used images for assessing wound healing in open fractures of the lower limb [68]. Images were reviewed by independent clinicians who were blinded to the treatment allocation. In these examples, images have been taken by nurses during follow-up home visits and transmitted to specialists in the hospital or the research team.

1.4.2. The use of digital images for diagnosing and monitoring SSI

The use of digital images for assessing surgical wounds is less common than other areas of wound care. A 2016 systematic review, for example, examined how telemedicine was used to facilitate recovery after a patient left hospital following surgery in the US [69]. From 21 included studies, the use of digital images for postoperative wound monitoring was reported in only two case series.

The use of digital images for diagnosing SSI is, however, an area of growing interest. A small number of studies have examined the use of digital images for assessing wounds for SSI. A study in the US explored the impact of a digital image of the wound on diagnostic accuracy of SSI [70]. Surgeons' SSI diagnosis based on a scenario of surgical history, physical exam and wound appearance was compared first without, and then with, accompanying wound images. The study demonstrated that diagnostic accuracy and

surgeons' confidence significantly improved with the addition of the images. This study, however, had some limitations. It used a scenario-based design rather than actual clinical cases. In addition, the wound images had been taken by a healthcare professional while the patient was still in-hospital, meaning its relevance to post-discharge wound assessment is unknown. A study undertaken in the US and Netherlands found that the use of wound images alongside clinical vignettes increased specificity but worsened accuracy and sensitivity for SSI diagnoses [71]. As with the previous study, this was based on scenarios using data collected from patients' hospital records. The study, did, however, use patient-generated wound images. For images to be used as a method for remote assessment of wounds post-discharge, patient provision of wound images would offer significant advantages. The following paragraph will now turn to the idea of the patient as the photographer and the provider of their own wound images after leaving hospital.

1.4.3. Patient provision of wound images

Advances in technology, including mobile devices such as smart phones, now provide an opportunity for patients to take and transmit images of their wound using their own devices. A high proportion of adults in the UK own or have access to a smartphone. The annual statistical survey published by Ofcom, the government-approved regulatory and competition authority for the UK communications sector, estimated that 78% of adults in the UK use a smartphone and 90% of people have access to the internet in the home [72]. Mobile phones are recognised as an ideal platform in telemedicine, with advantages of internet access, text messages, cameras, applications (apps) and the ability to connect to sensing devices such as digital scales and blood

pressure monitors [73]. Indeed, the emergence of 'medical selfies' and the concept of 'selfie telemedicine' have been reported in recent literature and media headlines [74].

The advantages of patient-taken images for remote wound assessment are clear. From the patient's perspective, the need to travel and take time off work for face-to-face visits is reduced. For healthcare providers, fewer clinic visits mean the burden on resources can be reduced, saving costs. The same advantages also apply to follow-up assessment in RCTs. Real-time monitoring of wound healing using images may also facilitate the earlier detection of problems [62].

1.4.4. Wound images as part of mobile phone 'apps'

Recent work in the US has specifically explored patient-provided images of wounds for SSI diagnosis using mobile technologies. Funded by the U.S. Health Technology Assessment (HTA) in 2017, work was undertaken to evaluate and define the roles of patient-generated health data (PGHD) and mobile devices in post-operative surgical care and SSI surveillance [75,76]. The programme of work included a review of the literature including a technical and market review of available post-operative mobile apps. The review identified 11 apps specifically developed for patients to report information about wound healing after surgery; with eight including a wound image as part of the app. Findings demonstrated that patient-submitted images were beneficial for identification of post-op complications and reducing readmissions. The use of apps for SSI surveillance and in research studies, however, have limitations because they come with financial

and resource use burden. As well as costs for the healthcare providers associated with initial purchasing and ongoing technical management the app, training for patients in how to use it may be required. Furthermore, patients may not always have the appropriate mobile devices to support the app [66].

1.4.5. Feasibility of obtaining patient-provided images

Several challenges exist surrounding the use of patient-provided wound images for the assessment of wounds for SSI remotely. Firstly, it may not be possible for all patients to take and transmit images. The process relies on patients having the appropriate device to take and transmit the image and the ability to use the device and technology. The capacity of the research team or healthcare service to receive and process the images is also critical. Secondly, there may be challenges surrounding the suitability of the image for assessing wounds for SSI. It is important that the image is standardised so that it is of adequate quality and clarity for clinical use and that relevant features of the wound can be examined [77-79]. Standardisation is important if there is a need to compare images over a period of time, often important for monitoring would healing [77]. Challenges in extracting clinically-useful wound features from non-standardised images taken by patients or their carers at home have been highlighted [78]. Different lighting conditions compared to clinical environments, for example, and patient positioning, obstructions and framing of the wound in the image are all issues that may affect the quality of the image. The authors report how these issues have not been addressed in existing literature. Image quality was one of the issues experienced in a pilot study of telemedicine for the management of chronic wounds in care homes

[80]. In this study, however, healthcare professionals were responsible for photographing the wound and authors reported the problems with quality related mainly to staff skills rather than camera quality. Evidence suggests, therefore, that high-quality instructions for patients are needed to ensure a clear, standardised wound image that it is clinically useful and fit for purpose is provided.

Some studies have explored patient views on the acceptability and feasibility of providing their own wound images remotely. A qualitative study with patients who had experienced post-discharge wound infection following abdominal surgery in the US explored patients' views on the acceptability of using a mobile application for identifying and managing wound complications after surgery [81]. The app included questions on symptoms and a function to take and submit a wound image. Interviews found that a wound monitoring application was highly acceptable to most participants. Some concerns were raised, however, including the lack of an appropriate device or problems with usability, such as difficulty using the application itself. The study findings are, however, limited by a hypothetical scenario and the use of paper mock-ups of the app, rather than participants being able to test a working version. The study had a relatively small sample size of thirteen participants. Other pilot work with patients undergoing general surgery has demonstrated that patients are willing to take and submit images of their wound for post-operative assessment [82].

Another example of a wound care application (a product called "Wound Check") for use after surgery, including the facility for patients to transmit a wound image, has been reported [83]. In a study with nine vascular and

general surgery inpatients, direct observation and user-feedback were used to examine patient usability of the app for post-operative wound monitoring. Findings demonstrated that patients were able to learn how to use the app and found it acceptable. Some difficultly was observed, however, in taking the image of the wound. Problems included confusion with changing the direction of the camera and achieving the optimal angle when taking the picture without assistance. This study examined the quality of the patient-provided images. Images were independently reviewed by three physicians to assess their suitability for diagnostic and treatment purposes. Although the number of images generated in the testing sessions were few (n=11), most images (n=9, 81.8%) were found to be sufficient by the majority of rating physicians. This study is, however, limited by its small sample size of nine participants and 11 wound images.

Lacking from the studies described above, however, is information on how patients were instructed to take the wound images. It is unknown whether they had considered the information patients might require to ensure the images of the wound were suitable and of sufficient quality to be clinically usable to assess the wound for SSI. The studies do not report whether instructions for patients, if any, were developed or provided. Only one study has provided detail on how patients were instructed to take images of their wounds and include the patient instruction sheet in a supplementary file to the publication [71]. Information on how these instructions were informed and developed, and whether they had been pre-tested with patients is, however, lacking.

Although emerging evidence for using patient-taken images for wound assessment is encouraging, the small number of studies and their limitations demonstrate there is more work to be done to explore the feasibility of obtaining and using patient-provided images as a method for assessing wounds for SSI. Feasibility work to explore whether it is possible for patients to: 1) take a clear and standardised image of the wound that is clinically usable and; 2) use their own device to take and transmit an image, is required to assess the potential of this method for assessment of wounds for SSI after the patient has left hospital.

1.5. Aims and objectives of thesis

Evident throughout this chapter is that reliable and valid methods for SSI assessment, specifically designed for patient-report after leaving hospital, are needed. A patient-completed measurement instrument for SSI that has been developed and validated specifically for use after hospital discharge is not currently available. The use of supplementary digital images for assessing wounds for SSI is an emerging area with many potential benefits for use post-discharge. Studies to date, however, have paid little attention to instructions for patients on how to photograph the wound and the important features that need to be considered when taking the photograph to ensure the images are standardised and provide images that are fit for purpose. Creating a reliable and valid SSI outcome measure will be valuable, particularly one that could be used both in hospital and post-discharge. It could be supplemented with patient-generated digital images for assessment of SSI remotely. This has the potential to provide a valuable contribution to SSI assessment for use in routine surgical follow-up, research and audit.

Aims

The aim of this thesis is to address the gaps and limitations of the current methods for SSI outcome assessment. Specifically, aims are to:

1) develop and validate an SSI outcome measure for patient or healthcare professional completion, suitable for use after the patient has left hospital;
2) develop and evaluate a method for patients to take and transmit a standardised image of their wound after leaving hospital, for remote wound assessment.

Objectives

Specific objectives of this thesis are:

1) to use mixed methods to inform the content and design of a new outcome measure for SSI suitable for completion by patients or healthcare professionals;
2) to pre-test the outcome measure with patients and healthcare professionals to explore acceptability, understanding and comprehensiveness;
3) to examine the measurement properties of the outcome measure in a large sample of participants after having surgery;
4) to develop a method for patients to take and transmit wound images:
    i) develop photography instructions for patients to take a standardised image of their wound after leaving hospital;

ii) adapt existing IT software for patients to transmit wound images to a research/healthcare team using their own mobile device;

5) to pre-test and refine the method for taking and transmitting images with patients;

6) to examine the feasibility, usability and acceptability of the method for taking and transmitting images with a large sample of patients after having surgery, including an examination of image quality.

These aims and objectives will be addressed in two studies. Study one will address the first aim to develop and validate a new outcome measure. Study two will address the second aim to develop and evaluate a method for patients to take and transmit wound images for potential use for SSI outcome assessment after hospital discharge.

1.6. Scope of the proposed work

Use of the outcome measure and method for obtaining patient-generated digital images are intended for SSI outcome assessment. The idea for this work was initially conceived within the context of a research study. It was considered that the methods could be applied in RCTs of interventions where SSI is a primary or secondary outcome. Study 1 was embedded in a wider study: the Bluebelle feasibility study [1]. This was a two-year National Institute for Health Research (NIHR)-funded feasibility study to explore whether it was possible to conduct a large multicentre randomised trial to compare the effectiveness and cost-effectiveness of different types of wound

dressings after elective surgery. The intended primary outcome was SSI occurrence within 30 days (The Bluebelle study, grant number 12/200/04, PI: Professor Jane Blazeby, supervisor of this PhD work). Patients with abdominal wounds were selected due to the higher associated risk of SSI in this population. Development and validation of an efficient and accurate SSI tool to use in hospital and post-discharge was one aim of the feasibility study. Appendix 6 includes a schematic overview of the wider Bluebelle study, showing how the development and validation of the SSI measure was one of its component parts. The Bluebelle study also considered the use of patient-provided images of wounds for potential use for blinded outcome assessment in a future RCT. A full investigation of the feasibility of this idea and develop a method for obtaining images from patients was not, however, possible within the remit of the two-year study. It was, therefore, considered a valuable study to explore in detail as part of this PhD research. Although the concept of the SSI outcome measure and use of patient-generated digital images originated within the context of a research study, it is anticipated, however, that these methods (with possible necessary modifications) for SSI outcome assessment may also apply to routine surgical practice, SSI surveillance and audit.

1.7. Summary

Without robust methods and measures to collect accurate, reliable and comprehensive information, data on SSI is at risk of being poor quality, unreliable and inaccurate, posing problems for SSI surveillance and research. This introductory chapter has described the extent of SSI as a clinical problem and the limitations of current methods for assessment of wounds for SSI after

patients have left hospital. The rationale for the research and aims and objectives of the current thesis are explained. Chapters 2 and 3 will now describe the methods and results of Study 1, relating to the development and validation of a new SSI outcome measure. Chapters 4 and 5 will then describe the methods and results of Study 2: the development and evaluation of a method to obtain digital wound images from patients. The sixth and final chapter of this thesis will bring these studies together, discussing the work in the context of recent literature, it's strengths and weaknesses, it's applications both in and outside of surgery and finally, recommendations for future research and areas for future work.

CHAPTER 2. METHODS: STUDY 1

DEVELOPMENT AND VALIDATION OF A NEW OUTCOME MEASURE FOR SSI

2.1. Introduction

An optimal approach to the development and validation of a new outcome measure involves both quantitative and qualitative research methods [46,84,85]. Emphasis is placed on ensuring that the measure has appropriate measurement properties, including content, construct and criterion validity, reliability and responsiveness, if relevant [46,86,87]. A more detailed description of these properties will be provided below. In the initial stages of development, specific methods may include an evaluation of existing tools and published literature to inform the content of a new measure. Qualitative interviews with key stakeholders can also identify valuable and unique information. Quantitative and statistical techniques are also generally considered important for testing the reliability and validity of a new measure and ensuring that is appropriate, fit for purpose and performs as intended.

This chapter gives a full account of the development and validation of a new SSI outcome measure. It describes established methods, applied to address the required essential properties of the new measure. A novel aspect of this

study is the design of a single 'universal-reporter' outcome measure, intended for completion by a patient or a healthcare professional.

2.2. Aim and objectives of the current study

The aim of the study was to develop and validate a new outcome measure for surgical site infection, for patient or healthcare professional completion. The intention was that it could be used either in-hospital, or, after the patient had been discharged. Specific objectives, as outlined in Chapter 1, relevant to the current study were:

1) to use mixed methods to inform the content and design of a new outcome measure for SSI suitable for completion by patients or healthcare professionals;
2) to pre-test the outcome measure with patients and healthcare professionals to explore acceptability, understanding and comprehensiveness;
3) to examine the measurement properties of the outcome measure in a large sample of participants after having surgery.

2.3. Essential properties of an outcome measure: a synopsis

Understanding of the essential properties of a high-quality outcome measure (measurement instrument) is well established [45,46,48,85]. A detailed description, therefore, is not intended to be included in this thesis. Instead, a

brief definition of each property and an explanation of its value is provided as follows:

i) Content validity

Content validity (including face validity) is defined as "the degree to which the content of a measurement instrument is an adequate reflection of the construct to be measured" [88]. Specifically, the outcome measure must be relevant, comprehensive (with no key aspects missing), and understood as intended [46].

ii) Construct validity

Construct validity is defined as "the degree to which the scores of a measurement instrument are consistent with a hypothesis, for example with regard to internal relationships, relationships with scores on other instruments or differences between groups" [88]. Construct validity can be described as three aspects: structural validity, hypothesis-testing and cross-cultural validity.

iii) Criterion validity

Criterion validity is defined as "the degree to which the scores of a measurement instrument are an adequate reflection of a gold standard" [88]. This is especially important for new outcome measures that are intended to have diagnostic accuracy.

iv) Reliability

Measures must be shown to be reliable, yielding reproducible and consistent data [86]. Reliability can be further categorised into test-retest reliability (that is, consistency across timepoints when no changes would be expected) and inter- and intra-rater reliability (that is, consistency across different and the same individuals, respectively).

v) Responsiveness

Responsiveness can be described as 'the ability of an instrument to detect change over time in the construct to be measured' [46]. This has relevance for outcome measures that intend to measure a construct that is expected to change, for example, after treatment.

vi) Acceptability

In addition to the established properties described above, another important property of an outcome measure is that it is acceptable to those intended to use it. It is essential that respondents are both willing and able to complete the new outcome measure. Acceptability is crucial to ensure there is a high level of data completeness and few missing data, essential for interpretation and generalisability of the findings [45,46].

Consideration of the measurement properties listed above in the development and validation of a new outcome measure is crucial to ensure that the measure is suitable, fit for purpose and ultimately can generate reliable and accurate data.

2.4. Methodological framework and use of applied methods

An existing, well-established framework for developing new outcome measures, with a particular focus on outcome measures intended for patient completion (PROMs) was applied [85,89]. The study was designed to ensure that the essential properties of the outcome measure described above were

addressed. Table 2-1 presents an overview of the methods that were applied to address each property. For the current study, responsiveness was not considered relevant to address. This was because the outcome measure was not intended to be used to detect changes over time in the context of its use as an SSI outcome measure in an RCT. A detailed description of the study methods follows in the rest of this chapter, in four chronological phases.

Table 2-1. Essential properties of an outcome measure including how and when these were addressed in the current study

Essential property	Applied methods to address property	Phase of study
Content validity	Analysis of existing SSI tools	Phase 1
	Interviews with patients and healthcare professionals	Phase 1
	Item formulation and design of preliminary measure	Phase 2
	Pre-testing using cognitive interviews with patients and healthcare professionals	Phase 3
Construct validity	Analysis of underlying scale structure (multi-trait scaling, factor analysis)	Phase 4
	Assessment of internal consistency (Cronbach's alpha coefficient)	Phase 4
Criterion validity	Comparison with 'gold standard' measure (sensitivity and specificity)	Phase 4
Reliability	Agreement between test-retest responses (Kappa statistic)	Phase 4
	Agreement between patient and healthcare professional responses (Kappa statistic)	Phase 4

Essential property	Applied methods to address property	Phase of study
Responsiveness	Not applicable to the SSI outcome measure within the intended context of use	n/a
Acceptability	Pre-testing using cognitive interviews with patients and healthcare professionals	Phase 1
	Examination of response rates	Phase 4
	Examination of missing data	Phase 4
	Debriefing questionnaire	Phase 4

2.5. Study design

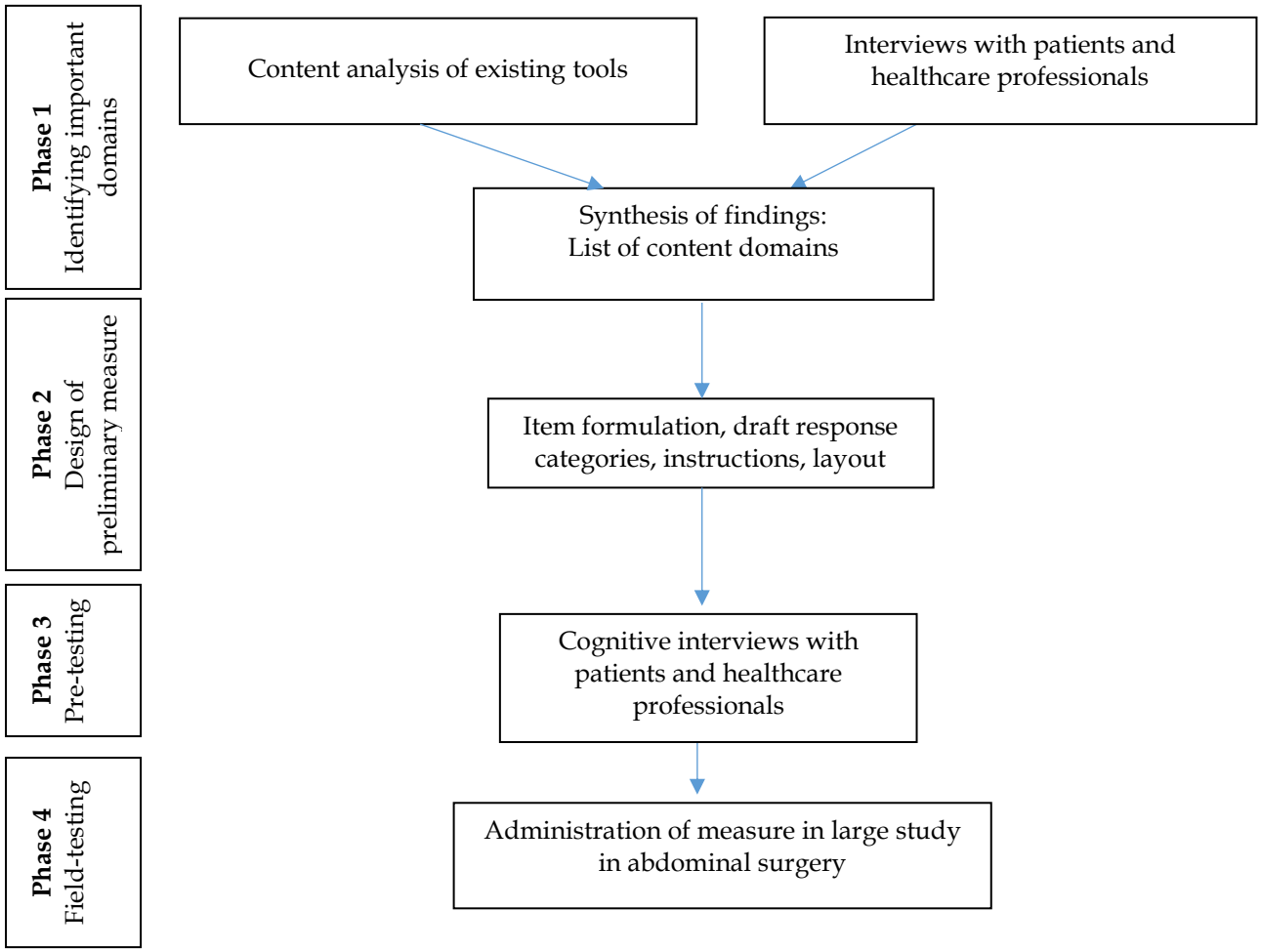
The overall design of the study was divided into four phases. A graphical representation of the study and each of the four chronological study phases are illustrated in Figure 2-1.

As described above, a novel characteristic of the new outcome was the intention that it could be completed by either a patient or a healthcare professional (observer). The study design and methodology, therefore, purposively involved all key stakeholders during each phase, an important and crucial consideration for ensuring that the new measure was fit for purpose.

- In Phase 1, potentially important domains (that is, aspects relevant to assessing wounds for SSI) were identified to inform the content of the new measure. Mixed methods were used, including:
    - i) an analysis of existing clinical and patient-completed tools commonly used to capture information for the assessment and diagnosis of SSI and;
    - ii) semi-structured interviews with patients and healthcare professionals with experience of SSI.
- In Phase 2, relevant domains derived from Phase 1 were operationalised into items for a provisional measure for completion by patients or healthcare professionals. Items were formulated in a novel way using lay language alongside medical terminology. A preliminary measure was drafted including response categories and instructions for completion.

- In Phase 3, the preliminary measure was pre-tested and refined in an iterative and cyclical process through cognitive interviews with patients and healthcare professionals.
- Finally, in Phase 4, the measure was field-tested (that is, administered to patients and healthcare professionals to examine its performance) in a large sample of patients undergoing abdominal surgery. Descriptive data summaries and statistical analyses were performed to validate the new outcome measure. Acceptability, reliability and construct and criterion validity in the target population were explored.

Figure 2-1. Phases of study for the development and validation of the SSI outcome measure.



2.6. Phase 1 - Identification of important domains: content validity

2.6.1. Objectives for Phase 1

The objective for this phase of the study was:

- to use mixed methods to inform the content and design of a new outcome measure for SSI suitable for completion by patients or healthcare professionals.

This phase of the study involved a mixed methods approach. Two different data sources (existing tools and qualitative interviews with patients and healthcare professionals) were used to identify the domains relevant for the assessment of wounds for SSI (for example, signs, symptoms and wound care interventions). The aim of using this comprehensive approach was to maximise content validity and ensure that an exhaustive list of all potential domains, important to patients and healthcare professionals, could be considered for inclusion in the new measure [45,46].

2.6.2. Content analysis of existing tools

Existing tools, such as existing health measurement instruments and questionnaires, serve as vital sources of information to help generate ideas and identify relevant issues to inform the content of a new measure [46,85]. A review of the content of the existing tools is therefore typically considered necessary in the first stages of developing a new measure, to identify potentially important content domains for consideration. Importantly, this

also ensures that an appropriate measure doesn't already exist, and duplicate work unnecessarily.

Identification of existing tools

An existing comprehensive systematic review of SSI definitions, grading scales and scoring systems, published by Bruce et al. in 2001 was used to identify the most commonly used existing tools for assessing SSI [31]. The review used robust methodology and detailed search strategies. Although several years since the review was conducted, expert knowledge within the wider study team and colleagues in the field (at universities and hospital trusts in Bristol and Birmingham) knew of no new definitions or tools that had been widely adopted. A scoping search of SSI literature was conducted before the current study to confirm that the findings from the Bruce et al. 2001 review were still demonstrated in current practice. This confirmed that the tools identified in the 2001 review continued to be the most commonly used tools, including those use by UK government agencies PHE and NICE [22,90]. Conducting a new systematic review was, therefore, considered not relevant for adding further value to the study.

Obtaining the source documents

At the time of this study, current versions of the tools were obtained electronically from the original published papers and via links on the associated websites giving accessibility to the documents online. Further details will be provided as part of the study results and presented in the following chapter.

Data extraction

To perform the content analysis of existing tools, verbatim text of the specific clinical criteria or questionnaire items used for the assessment of SSI were first extracted from the source documents. All corresponding response categories were extracted. Data were transcribed verbatim into a Microsoft Excel spreadsheet. Data extraction was performed by the author of this thesis.

Data analysis: categorisation into SSI domains

Inductive, open coding of extracted textual data was conducted, a commonly used method to identify content for outcome measure development [85,91]. This means that data were labelled using content-characteristic words and subsequently organised into groups or categories (domains) defined as broad aspects of the effects of SSI on a patient [92]. Methods followed a framework for grouping data into domains that is often used to develop core outcome sets [93-95]. This involves scrutinising text within items or criteria on an individual basis (rather than considering any pre-defined grouping into domains by the developers of the original questionnaire or tool) [96]. This technique aims to ensure that the actual issue being addressed by each item or criteria is considered independently and at face value. An inductive approach meant that grouping and categorisation into domains was driven by the data and not pre-defined prior to the analysis [91]. This approach was taken so as not to influence the emergence of any important domains which may have not originally been conceived by the author of this thesis. Grouping data into domains was done initially by the author of this thesis and verified by the wider study team to ensure robustness and validity of the analysis.

2.6.3. Interviews with patients and healthcare professionals

Qualitative interviews with key stakeholders are commonly used as a valuable method and source of information to identify relevant and important content domains to include in the development of a new outcome measure [46]. Used alongside other data sources, such as a content analysis of existing tools, data from interviews can be included to maximise content validity of the new measure. Interviews can provide a rich source of data, gathering expert opinion, knowledge and unique experiences directly from key stakeholders including, for example, patients and healthcare professionals. Interviews provide an opportunity to explore reasons that stakeholders consider certain domains to be important, i.e. why they should be included. As described in Chapter 1, existing SSI questionnaires for patients had not included patients in their development. A particular objective of the patient interviews was, therefore, to identify important aspects for assessing SSI from the perspective of the patient. The intention was that interview data would supplement the data extracted from the existing tools and identify any potential additional content domains not included in the existing tools. This was to ensure the list of content domains to consider for inclusion in the new outcome measure was as comprehensive as possible, and included issues considered to be important to patients as well as healthcare professionals [46]. The key aim of the interviews in the current study were for content generation for the new outcome measure and to identify a list of themes relevant to assessing wounds for SSI for consideration alongside the data obtained from the content analysis of existing tools. The interviews were not intended to develop theory or gain a full understanding of patients' and healthcare professionals' experiences of SSI and views of SSI assessment.

Key stakeholders

As detailed above, a key objective and novel characteristic of the new measure was that it was intended to be a single 'universal' measure, appropriate for completion by a patient and/or healthcare professionals. It was considered essential that important content domains were, therefore, explored from the perspective of all key stakeholders. Key stakeholders included both patients and healthcare professionals with experience of SSI and post-surgical wound care. Patients were included as they served as experts with direct personal experience of symptoms and severity of SSI and the impact of SSI on quality of life and function. The perspectives of patients were considered to be especially important in this study as existing tools have lacked patient input in their development, as described in the first chapter of this thesis. Healthcare professionals were included to ensure that the expert opinion and views of those managing and treating patients with surgical wounds and SSI were sought, to ensure all relevant domains could be identified and considered for inclusion in the new measure.

Sampling and identification of potential participants

Patients

Patients who had undergone abdominal surgery and had developed or had recent experience of a wound infection were sampled to take part in interviews. Abdominal surgery was selected due to the high rate of SSI in this speciality. This covers a broad range of surgical procedures and patient characteristics, offering a wide range of perspectives to explore. Types of surgeries include open and laparoscopic procedures, including appendectomies, bowel resections, and caesarean sections. Patients

experiencing SSI, as indicated in hospital records, were identified and approached for study participation by surgical trainees or research nurses involved in the wider Bluebelle study (in which this study was embedded, as described in Chapter 1; Section 1.6). Patients were approached on wards and in clinics at University Hospitals Bristol NHS Foundation Trust. Participant information leaflets describing the study were provided (Appendix 7).

Healthcare professionals

An opportunistic and snowballing approach to identify healthcare professionals was taken, in which potential participants were identified through personal knowledge (that is, healthcare professionals known to the study team as well as further recommendations of potential participants from those taking part in interviews). From those identified, a purposive sample of healthcare professionals was selected to ensure maximum variation in their characteristics and experience, including their roles working in primary or secondary care and within different clinical specialties (for example, gastrointestinal surgery and obstetrics).

Recruitment and consent

Details of individuals who had expressed an interest in participating in the study were recorded on a study database, purpose-built as part of the wider Bluebelle study by the person who had approached the individual (the trainee or research nurse in the case of patient participants). Participants were contacted by a qualitative researcher (A.N.) to further discuss the study and arrange a face-to-face interview. The time and location to conduct the

interview was arranged to suit the participant, either at the participant's home or on hospital premises.

The involvement of a qualitative researcher to arrange and conduct the interview component of this study (rather than the author of this thesis) was necessary due to the timing of the work and the fact that it was embedded within the wider Bluebelle study. There was a need to adhere to timelines and the author of this thesis was unavailable at this time due to maternity leave. The qualitative researcher (A.N.) was a member of the Bristol Medical School and was experienced in health services research and conducting interviews for developing new outcome measures.

Participants were invited to provide written informed consent by the qualitative researcher at the time of the interview, allowing for further discussion and following time for asking questions, before the interview was conducted.

Research ethics approval was granted from the NHS Health Research Authority NRES Committee London – Camden and Kings Cross (reference 14/LO/0640).

Data collection

Interviews took a semi-structured form using topic guides (separate for patients and healthcare professionals), pre-written specifically for the study by a qualitative interviewer (A.N.) and informed by the content of existing SSI tools and literature (Appendix 8 and Appendix 9). Topic guides were used to ensure that interviews explored similar topics with each interviewee, with

flexibility to allow new emerging topics or issues of relevance to the individual interviewees to be discussed. This approach allowed for topic guides to be updated as the study developed to include new topics that arose in previous interviews. The topic guide used for the patient included an overview of the interviewee's background and surgery details, their experience of wound infection, experience of common SSI signs, symptoms, severity of wound infection and problems, exploration of health care use, interventions and investigations (Appendix 8). The topic guide for interviews with healthcare professionals included an overview of the interviewee's background and surgical expertise, the typical signs, symptoms considered indicative of infection and the interventions and care pathways used to treat infections (Appendix 9).

During interviews, participants were shown existing tools commonly used in current practice for assessing SSI. These tools were identified by the methods described above and will be described in more detail in the following chapter. Patients were shown the PHE SSISS post-discharge questionnaire for patients [22] (Appendix 4) and items from an ASEPSIS-associated patient questionnaire [57] (Appendix 5). Healthcare professional participants were also shown the PHE SSISS list of SSI criteria [22] (Appendix 15) and the ASEPSIS grading scale [51] (Appendix 16). The interview topic guides included prompts to elicit feedback on the relevance, ease of completion and understanding of criteria and items in the commonly used existing SSI tools. Views on the item wording used in the tools were sought in order to identify any potential issues with comprehension and acceptability of the language used to inform the phrasing of items for the new outcome measure.

Interviews were audio-recorded using an encrypted Olympus DS-3400 digital voice recorder. Recordings were transferred for storage on secure password-protected computers and networks at the University of Bristol, accessible only by relevant study personnel.

Data analysis: identifying themes relevant to the content for the new outcome measure

Audio-recordings were transcribed in full by a research secretary with experience in transcribing qualitative interviews at the Bristol Medical School, University of Bristol. Transcripts were anonymised (removing any mention of names or hospitals) so that participants could not be identified, using a unique numerical identifier. Transcripts were analysed by the qualitative researcher (A.N.) conducting this part of the study. A thematic approach was taken to the qualitative data analyses, a method for organising and grouping the data often used for interview data [91]. First, transcripts were read and scrutinised. Data were coded or 'labelled' with context-specific labels using an inductive approach (as described earlier), a common approach to analysing qualitative data for the development of outcome measures [85]. Next, codes/labels were further grouped into themes (that is, data that shared similarities relevant to SSI diagnosis), for example, data relating to SSI signs, symptoms or wound care interventions. Lastly, a list of themes relevant to the assessment and management of wounds for SSI was produced. Participants' views on the existing tools and any relevant issues or information raised in the interviews considered by the researcher to be important to consider for the development of the new outcome measure were summarised in a descriptive account. The descriptive account was updated as more interviews were undertaken. The purpose of the interviews was to identify relevant

content domains for the new measure. A detailed narrative was, therefore, not intended, in line with the use of these methods for the development of other outcome measures [85,89]

To maximise robustness of the qualitative research and reflexivity of the interviewer when conducting and analysing data, findings were routinely shared and discussed with the study supervisors during the iterative cycle of data collection and analysis. This was to minimise any undue impact or influence of the researcher on the collection and analysis of the data, a common consideration for qualitative research [97].

Interviews and analyses were performed in an iterative cycle drawing on the constant comparative method of qualitative analysis [98]. Small numbers of interviews were conducted and analysed before conducting the next set of interviews. This approach allowed new data to inform topics for discussion in subsequent interviews. Information gathered from previous participants could then be used to explore whether the topic was a shared experience and to discuss its importance for SSI assessment. This is a well-established method and technique and is an approach commonly used for outcome measure development and generation of content domains [46].

2.6.4. Synthesis of findings

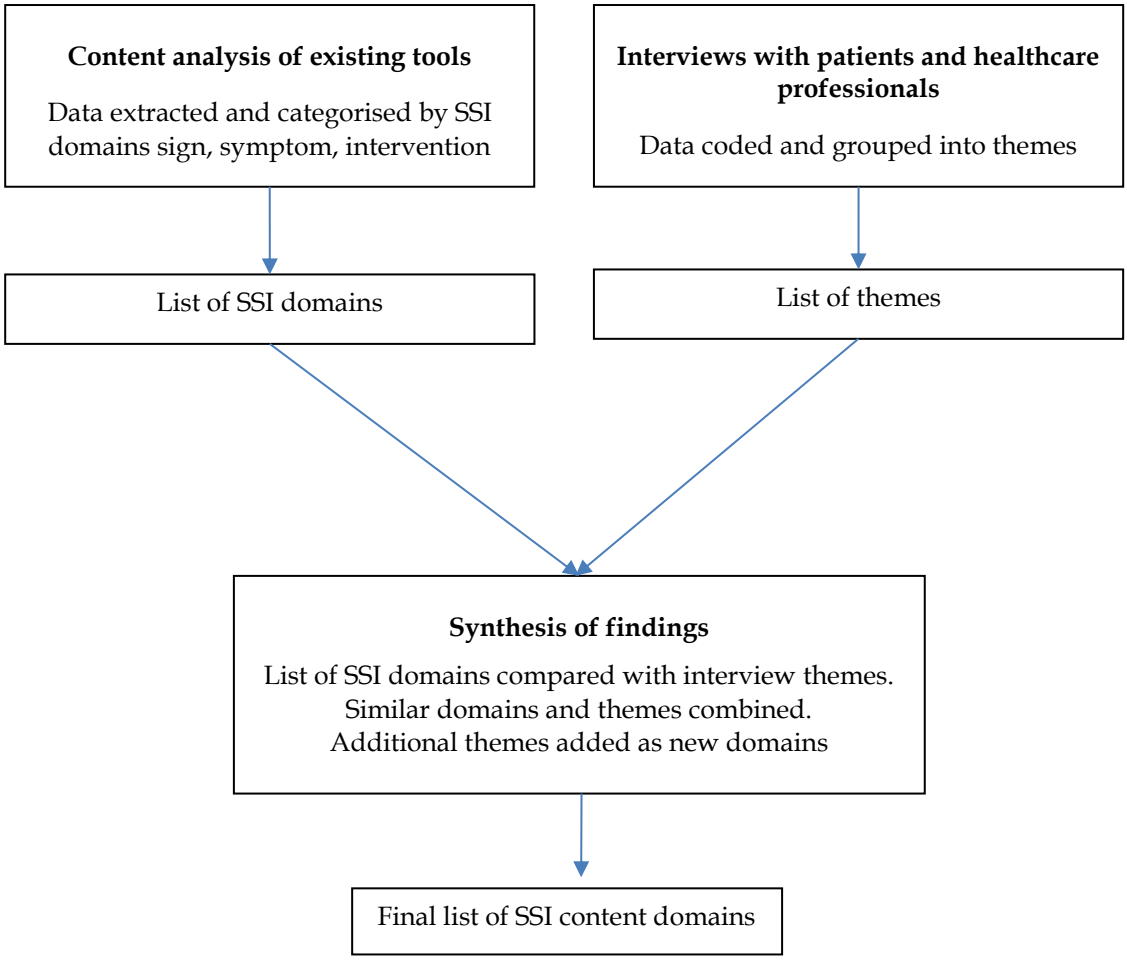
Findings from the content analysis of existing tools and interviews with key stakeholders were combined by the author of this thesis to ensure identified domains were considered from both of the data sources, maximising content validity of the new measure. A schematic diagram representing the different

data sources, methods to identify data, and how data were synthesised is shown in Figure 2-2. Findings were initially combined by the author of this thesis and verified by discussion with the study team to ensure methodological rigour in the following way:

i) First, the list of themes derived from the interview data were mapped onto SSI domains identified from the content analysis of existing tools. Mapping was performed when the theme reflected with, corresponded to, or added complimentary information to, any of the SSI domains.

ii) Next, any themes that could not be mapped to an existing domain were added as a new domain. The descriptive terms used to define domains were broadened or narrowed to be more specific when necessary, to integrate findings from both sources.

Figure 2-2. Synthesis of data to inform content domains for the SSI measure



2.7. Phase 2 – Designing the preliminary measure: content and face validity

2.7.1. Objectives for Phase 2

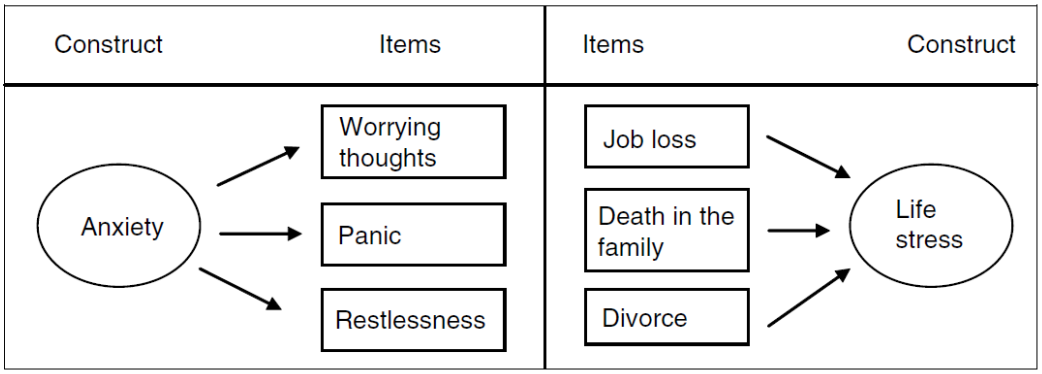
The objective for this phase of the study was:

- to design the preliminary outcome measure, ready for pre-testing in Phase 3.

2.7.2. Conceptual framework

The conceptual framework for the new SSI measure was based on a reflective model. This means that the underlying relationship between the items and the construct of interest (SSI) was considered to be reflective; that is, the construct is expressed or reflected by the items, rather than 'causing' the items as in the case of a formative model [46]. Figure 2-3 describes these two types of models in a graphical form. Consideration of the conceptual framework is important when generating items for a new measure and how they will be phrased. The conceptual framework also plays an important part in determining the measurement theory and suitable analysis plan for evaluating a new measure [46]. The reasons for this will be described later in this chapter.

Figure 2-3. Conceptual frameworks for relationships between constructs and items



Reference: de Vet et al. 2011 [46]

Key considerations for designing the measure

After completion of Phase 1 of the study and a comprehensive list of domains considered important for inclusion in the new measure had been established, Phase 2 focused on formulating the items and designing the preliminary version of the measure. This phase was important for considering face validity and future acceptability of the measure as it involved the wording and formatting of its content. Specific steps included:

i) the conversion (operationalisation) of domains into items (questions);

ii) defining suitable response categories;

iii) drafting instructions for how to complete the measure, and;

iv) general formatting and layout, including the order of items.

2.7.3. Operationalisation of domains into items: a novel approach combining plain language and medical terminology

As described previously, a key objective and novel aspect of the new measure was that it was intended to be a single 'universal' measure, appropriate for completion by a patient and/or a healthcare professional. The rationale for this approach was to reduce the potential risk that separate tools, with items written using different terminology and language for patients and professionals, may be interpreted differently and therefore measure a different or slightly different underlying construct than intended. To address this, domains identified in Phase 1 were initially 'operationalised' into items (questions) that could be easily read and understood by patients. This is a standard approach for designing a PROM that is intended to be completed by patients and not healthcare professionals. Items were phrased using plain language with the intention of being clear and unambiguous. Phrasing of items in existing SSI tools (identified in Phase 1) was considered, in conjunction with findings from the Phase 1 interviews (where views and suggestions on the wording of items in existing tools had been sought). In addition, and of specific relevance to the development of a single outcome measure that was intended for patient or healthcare professional completion, a novel approach was taken to include the medical terminology for the sign, symptom or intervention intended to be measured (when one existed) at the end of item in parentheses. Medical terminology was informed by existing clinical tools, literature and expert knowledge within the study team. This novel approach to questionnaire design has been pioneered in previous research conducted within the Bristol Medical School (in which the author of this thesis was involved) where the views of patients and professionals on the

same subject is needed, for example in the development of stakeholder surveys to prioritise health outcomes for inclusion in core outcome sets [93,95,99].

Phrasing of items was performed by the author of this thesis and members of the study team with expertise in developing and using patient-reported outcome measures and expertise in the assessment of SSI.

2.7.4. Response categories

For items addressing signs and symptoms, an initial five-point ordinal response category ('not at all', 'a little' 'moderately', 'quite a bit' 'very much') was used. These categories were chosen based on existing Likert scales commonly used in patient-completed questionnaires to assess health-related quality of life and symptoms. However, the methods sought to explore the appropriateness and relevance of using this type of response category compared to dichotomous yes/no options in the pre-testing stage of the study (described below, Section 2.8). For items addressing wound healing interventions, conditional yes/no response options were used, with the addition of a 'don't know' option to examine whether individuals were unaware of any interventions that may have occurred or did not understand the item description; an important consideration when testing item acceptability [86].

2.7.5. Instructions for completion

Appropriate written instructions on how to complete items are just as important to consider and test as the items in the outcome measure themselves. This is to ensure that the individual providing the data completes the outcome measure as intended and provides appropriate and relevant information [45,46]. Several issues needed addressing clearly in the instructions for the purpose of this study. Firstly, instructions asked the respondent to complete the items in relation to their main surgical wound. In cases where the participant has more than one wound and healing of a wound other that the main wound had been problematic, respondents were instructed to complete the items in relation to the problematic wound. This was to ensure that the measure captured the information that would be required for assessing whether SSI had occurred on an individual level (that is, per participant) rather than a wound-based level (that is, per wound). Accounting for SSI on an individual level is how the measure would be intended to be used in research studies and clinical practice, where it is typically the number of patients that experience SSI that is reported [20,22,27]. Secondly, in the preliminary version of the measure to be tested, instructions requested the respondent to consider what had happened to the wound since leaving hospital after having surgery. This was in order to have a fixed time period for participants to recall what had occurred, an important consideration for collecting data in questionnaires and surveys and an important consideration for internal validity of an outcome measure [46,100].

2.7.6. Draft of the preliminary measure

A preliminary version (1.0) of the measure (expected to change during subsequent pre-testing in Phase 3 of the study as described below) was drafted by the author of this thesis and presented to the study management group of the wider Bluebelle study team for comment and suggestions for improvements. Feedback on the items, wording, response categories, design and layout was obtained, and minor modifications were made to the measure until it was considered ready to pre-test with a sample of potential respondents.

The measure for participant and healthcare professional completion was identical, with the exception of the use of first- or third-person narrative in items (for example, "Has your wound…" or "Has the wound…"). This was necessary to make the tool appropriate for completion by a patient or an observer.

2.8. Phase 3 - Pre-testing the measure: content and face validity

2.8.1. Objectives for Phase 3

The objective for this phase of the study was:

- to pre-test the outcome measure with patients and healthcare professionals to explore acceptability, understanding and comprehensiveness.

To ensure that items in the preliminary version of the measure were understood, acceptable, relevant and comprehensive, Phase 3 of the study pre-tested the measure with a sample of potential respondents. This served as a test of content validity, including face validity [45,46]. Pre-testing was performed in one-to-one cognitive interviews, an established technique for testing new questionnaires and measurement instruments and recognised as an ideal method to identify and correct any problems [45,101]. A novel characteristic of the measure and, therefore, essential to explore in this phase, was the combined use of plain language and medical terminology in items.

Specifics objectives of the pre-testing phase were to:

- Check interpretation and understanding of items as intended for the underlying issue being assessed;
- Identify potentially confusing items or items that were difficult to complete;
- Ensure that the plain language descriptions were an accurate reflection of the included medical terminology and vice versa;

- Ensure acceptability of the length, format and response categories for effective completion of the measure;
- Obtain general feedback and suggestions for improvement;
- Explore views and acceptability on the novel approach to developing a single 'universal' tool for patient and healthcare professional-completion, and the combined use of plain language and medical terminology.

2.8.2. Participants and recruitment

Sampling

Patients and healthcare professionals were sampled to pre-test the preliminary version of the measure. Potential participants were sampled to be representative of the target population intended to use the measure. This included patients who had recently (within 30 days) undergone general abdominal surgery or had given birth by caesarean section and healthcare professionals involved in post-operative wound care and assessment. This timepoint was selected as it is the widely accepted timeframe for expecting SSI to have occurred [32]. It was appropriate, therefore, to pre-test the measure with patients within this timeframe as it reflected when the outcome measure would be intended to be used in research and routine practice.

Patient participants were sampled using an opportunistic approach from post-surgical general and obstetric recovery wards at University Hospitals Bristol and North Bristol Hospital NHS Trusts. A variety of patients undergoing different surgical procedures and professionals from different specialties were sought to maximise variation in demographics and types of wounds in the sample. A purposive sample of healthcare participants were selected to ensure maximum variation in participants' professional roles and clinical specialties. These sampling techniques ensured that pre-testing could be conducted in a sample representative of the wider population intended to complete the measure as much as possible [101].

Identification of potential participants

Identification of potential patient participants and distribution of study information leaflets (Appendix 7) was performed by surgical trainees and research nurses involved in the wider Bluebelle study. Contact details of interested participants were passed on to the author of this thesis or a surgical trainee involved in this phase of the study (T.M.) as part of an academic placement with the Bristol Medical School. Potential healthcare professional participants were identified through suggestions from members of the Bluebelle study team and management group or through suggestions from the author's professional colleagues at the Bristol Medical School.

Recruitment and consent

Study researchers (the author of this thesis and T.M.) contacted potential patient participants by telephone after they were discharged from hospital. Interested healthcare professionals were contacted primarily by email. Further explanation of the study was provided and a suitable date, time and location for an interview (offered to be either at patients' own homes or on hospital or university premises, as convenient to the participant) was arranged with those agreeing to take part. Written informed consent was taken by the researcher at the time of the actual interview.

2.8.3. Data collection

Cognitive interviews were primarily conducted by the author of this thesis, with a minority conducted by a surgical trainee involved in this phase of the study (T.M.). Interviews were conducted face-to-face either at patients' own

homes or on hospital or university premises (at the preference of the participant).

During interviews, participants were asked to complete the preliminary outcome measure using a 'think-aloud' approach [101]. This required participants to verbalise their thought process as they read and responded to each item. Participants were, for example, asked to explain their interpretation and level of understanding (comprehension) of the item and the justification for their response. This approach allows for observation of any problems with specific items or issues raised, and is a common technique used for pre-testing questionnaires and surveys as it allows for the identification and understanding of any potential confusion, misinterpretation or problematic items [45,101]. On completion of the measure, the interviewer returned to any relevant items and asked probing questions to further explore understanding, accuracy and interpretation of the items, for example, asking "what does…[a word]… mean to you?". Opinions on the combined use of plain language and medical terminology in items were specifically sought to explore this novel aspect of the new measure. General comments about the measure were also asked for, including the relevance of items to participant's experiences (to explore whether all items were considered to be important), comprehensiveness of the items (to investigate whether any aspects relevant to SSI were missing), ease of completion, and suggestions for changes or improvements. A structured topic guide was developed and used flexibly to guide interviews to provide some consistency and ensure that the objectives of the interview were met, whilst allowing for modifications and adaptability across participants [101] (Appendix 10). Iterations were made to the topic guide throughout the course

of the interviews to allow flexibility and responsiveness to any emerging findings from previous interviews [101].

Interviews were audio-recorded using a digital voice recorder (Olympus DS-3400). Recordings were stored as encrypted files on the device until they were transferred on to password protected computers and secure network space at the University of Bristol. Hand-written notes documenting any observed issues were made by the researcher while observing the participant complete the measure, so that problems or areas of interest could be explored further with the participant within the same interview [101]. Further written notes were made by the researcher within a short period after conducting the interview to record any relevant observations or personal notes about the process to supplement interview data and record any reflective information that might aid later analysis.

2.8.4. Data analyses

Each cognitive interview was listened to and summarised by the author of this thesis in a descriptive a memo, including;

- the time and setting of the interview;
- a brief summary of the surgery and wounds;
- any details or direct issues considered relevant to how the measure might be completed or responses given;
- key points for how the measure might be improved
- selected verbatim quotations relevant to the combined use of plain language and medical terminology in items to allow a more in-depth analysis and apply a thematic approach to analyse this novel aspect of the measure in more detail.

Interviews and analyses were conducted simultaneously in a cyclical, iterative manner [102]. Descriptive memoranda were scrutinized after approximately every three interviews for any issues or repeated key points for improvements that emerged. Modifications to the measure (if required) were made to reflect the emerging findings and a new preliminary version (version 1.1, 1.2, 1.3 etc) of the measure was then provided to new participants participating in subsequent interviews (rather than modified versions of the measure being tested by the same participants). Interviews were conducted until no further substantial issues were identified or changes to the measure were required [101].

During Phases 1- 3 of the measure development, members of the immediate study team (experts in the development and/or use of PROMs in clinical trials, trial methodologists and experts in SSI) met routinely to discuss progress and findings. The preliminary version (1.0) and subsequent modified versions during pre-testing were circulated to the team and comments and suggestions for improvements were invited. Findings were also presented at coinciding full team meetings for the wider Bluebelle feasibility study, and comments and suggestions for improvements were invited from the wider study team (including nurses, surgeons, qualitative researchers, health service researchers and study management staff). Comments and suggestions were collated and considered by the immediate study team and adopted into the next modification of the measure during pre-testing (Phase 3).

2.9. Phase 4 - Field-testing the measure: acceptability, reliability, construct and criterion validity

2.9.1. Objectives for Phase 4

The objective for this phase of the study was:

- to examine the measurement properties of the outcome measure in a large sample of participants after having surgery.

In line with the established methodological framework followed for this study [85,89], after pre-testing and making any required modifications to the new measurement instrument, the final stage of its development was to distribute the instrument to a larger sample of the target population. This process is known as 'field-testing'. It serves to further assess the performance of the outcome measure, including acceptability, reliability and further types of validity such as construct and criterion validity in a more 'real-world' setting with a sample representative of the target population [46]. Using the measure to collect data on a large number of patients after undergoing surgery provides a better insight of the measurement properties of the outcome measure than can be gained from pre-testing with a small sample using qualitative methods, and allows for a quantitative analysis of the performance of the measure as it would be expected to be used in practice [46].

2.9.2. Study design

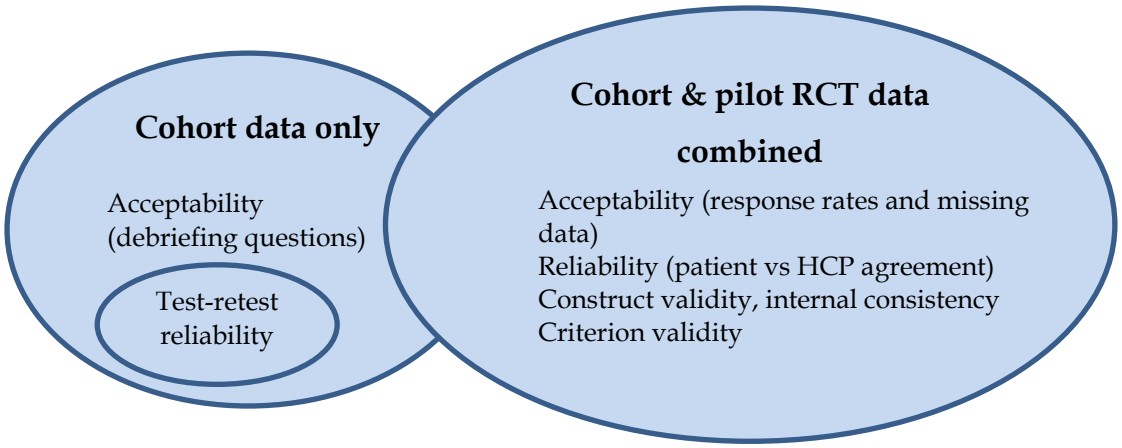
Field-testing of the provisional SSI measure (version 2.0) was undertaken by administering the measure in two prospective, multicentre studies in order to maximise data available for evaluation. These were;

i) a cohort field-testing study, and;

ii) a pilot randomised controlled trial (RCT)

Both studies were embedded within the Bluebelle feasibility study. As detailed previously in the introductory chapter of this thesis (Chapter 1), the Bluebelle study was exploring the feasibility of conducting a large RCT of different wound dressing strategies after abdominal surgery. The cohort field-test study was specifically designed to evaluate the new SSI measure, and assess whether it was possible to collect reliable and valid SSI outcome data post-discharge. The pilot RCT was designed to assess whether it was possible to conduct a large RCT of different types of dressing strategies (the main aim of the Bluebelle study), with administration of the new SSI measure included to maximise data for its evaluation. Participant eligibility criteria, described below, were similar in both studies making the datasets acceptable to combine. The same provisional version of the SSI measure (version 2.0) was administered to participants in both studies. Figure 2-4 demonstrates how the two studies contributed to evaluating the different properties of the measure.

Figure 2-4. Measurement properties addressed using data from the cohort study alone, and combined data from the cohort and pilot RCT studies.



2.9.3. Participants and recruitment

Sampling

i) Cohort field-testing study

Eligible participants were patients who had recently undergone surgery and met the following inclusion criteria:

1. Aged 18 or over;
2. Had undergone elective or unplanned abdominal surgery (including, but not limited to gastrectomy for benign or malignant disease, cholecystectomy, small or large bowel resection for benign or malignant conditions, abdominal wall hernia surgery (inguinal, femoral, incisional, epigastric and paraumbilical) or elective or unplanned obstetric surgery (caesarean section);
3. Had undergone surgery by standard open, laparoscopic or laparoscopically-assisted surgical method;
4. Willingness to have a home visit and/or attend follow-up at 15 and 30-days.

Patients could not enter the study if any of the following applied (exclusion criteria):

1. Prisoners;
2. Adults lacking capacity to consent;
3. Lack of ability to read/understand English that would preclude successful completion of questionnaires.

ii) Bluebelle pilot RCT

Eligible participants were patients about to undergo surgery and met the following inclusion criteria (to comply with the aims of pilot the RCT):

1. Aged 16 or over;
2. Undergoing primary elective or unplanned abdominal general surgery (including, but not limited to gastrectomy for benign or malignant disease, cholecystectomy, anti-reflux procedures, hepatic resection, small or large bowel resection for benign or malignant conditions, abdominal wall hernia surgery (inguinal, femoral, incisional, epigastric and paraumbilical)) or elective or unplanned obstetric surgery (caesarean section);
3. Willingness to attend follow-up for 4-8 weeks.

Any of the following criteria made the patient ineligible (exclusion criteria), the majority being relevant to the purpose of the pilot RCT for the wider Bluebelle study:

1. Had undergone abdominal or other major surgery less than three months before the index operation;
2. Intention to 'close' the wound with tissue adhesive (glue);
3. Had an allergy to dressings or another contraindication to dressing allocation;
4. Undergoing surgery where no skin incision occurs;
5. Prisoners;
6. Adults lacking capacity to consent;
7. Lack of ability to read/understand English that would preclude successful completion of questionnaires.

Identification of potential participants

Potential participants were identified and approached by research nurses or surgical trainees (from the regional surgical trainee collaboratives) involved in the wider Bluebelle study. Participants were identified from hospital wards or in clinics within a few days before or after surgery. In the cohort study, participants were identified from three UK hospital trusts, over a period of six months between August 2015 and January 2016. In the pilot RCT, participants were identified from four UK hospital trusts over a period of nine months between March and November 2016. Participant information leaflets (Appendix 11) describing the study were provided and enough time to read, discuss the study and the opportunity to ask questions was given.

Recruitment and consent

Potential participants were re-approached by research nurses or surgical trainees. Those expressing an interest in participating were recruited. All participants were asked to provide written informed consent at the time of recruitment (Appendix 12). Ethics approval was granted by the South West – Frenchay Research Ethics Committee (reference 15/SW/0008).

Data collection

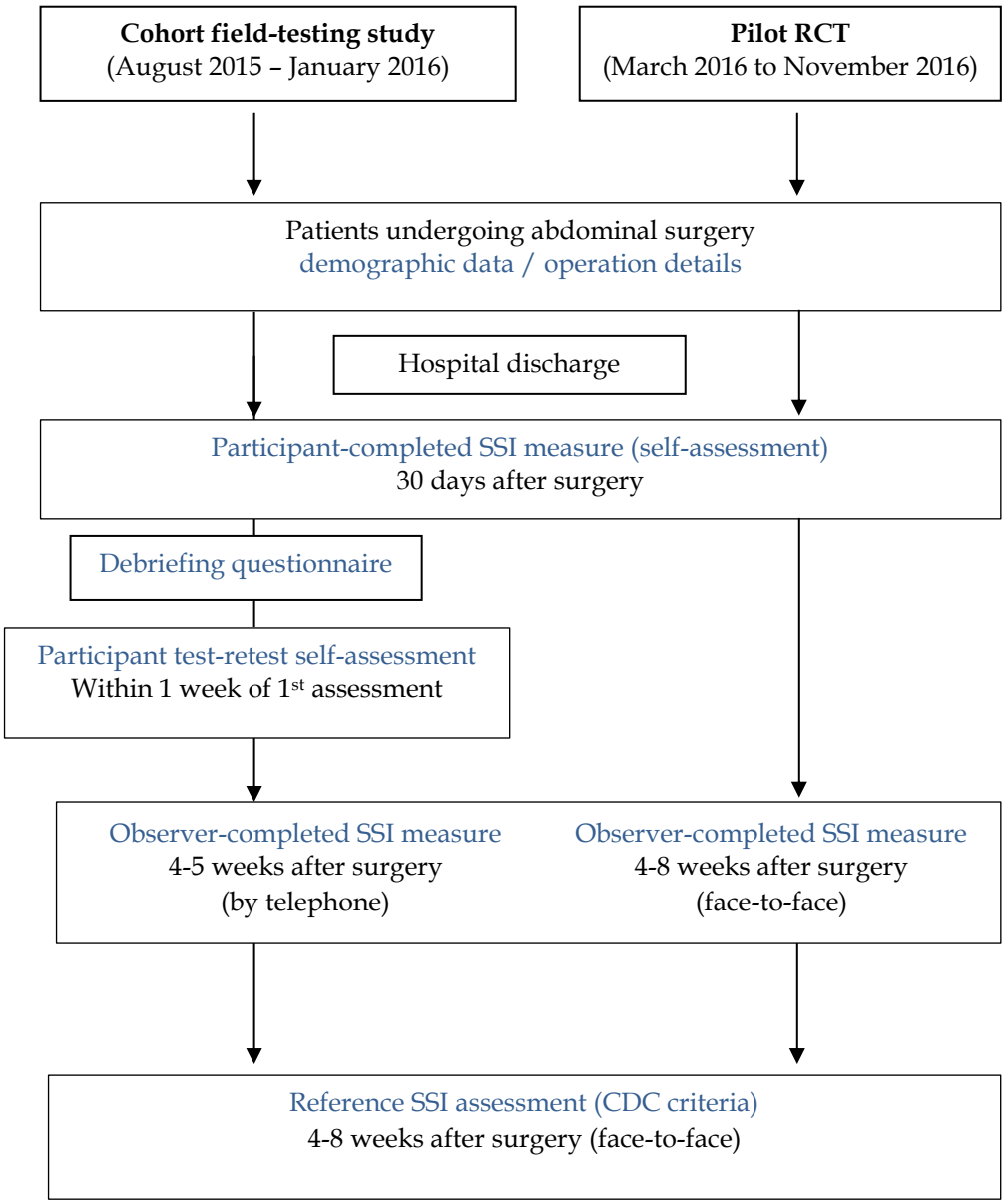
A schematic overview of the data collection for the cohort and pilot RCT studies is shown in Figure 2-5. The new measure was administered to participants as a postal questionnaire to provide a self-completed assessment of their wound. The measure was also completed by healthcare professionals during follow-up telephone calls or in follow-up face-to-face appointments with participants to provide an observer-completed assessment of the

participants' wound. A more detailed description of data collection and how data were analysed follows shortly under different subheadings pertaining to the different measurement properties being evaluated.

Participant demographics

Details of participants' sex, age, marital status, employment status, smoking history, diabetes and physical status (American Society of Anaesthesiologists; ASA classification [103]) were collected from hospital records or directly from the participant by research nurses or trainee surgeons involved in the wider Bluebelle study. Basic operative details were recorded including elective or unplanned procedure, operation type, operation classification (clean, clean-contaminated, dirty), open or laparoscopic, duration of operation and peri-operative analgesia use. These data were collected in order to describe the basic characteristics of the study sample and to make comparisons between groups in later analyses.

Figure 2-5. Data collection in the cohort and pilot RCT studies contributing to validation of the SSI measure



Datasets and data preparation

Data from the cohort field-testing study and the pilot RCT were combined into a single dataset to evaluate the specific properties of the new measure (described in each subheading below), where applicable. Assessment of some measurement properties, however, such as test-retest reliability, were limited to data from the cohort study alone because data to examine these properties were not collected as part of the pilot RCT design (Figure 2-5).

Responses to items in the new measure were assigned values or 'scores' in order to perform quantitative data analyses. For items with an ordinal response category (items assessing symptoms), assigned values to the categories were on 4-point scale: 'not at all'=0, 'a little'=1, 'quite a bit'=2, 'a lot'=3. For items with conditional responses (items assessing wound care interventions), assigned values were 'no'=0 and 'yes'=1. These values were selected with the rationale that any participant who did not experience any symptoms or did not require any wound care interventions would have an overall summative score of zero. Interpretation of the overall score would, therefore, have a baseline score of zero making clinical and logical sense. Incremental unit values of one were assigned to the response categories in an order of increasing 'severity'. The degree of severity between each category of 'not at all', 'a little', 'quite a bit' and 'a lot' was assumed to be equal for purpose of analysis, in line with scoring of other similar health-related quality of life questionnaires using similar response categories [104,105]. Responses of "don't know" were re-coded as missing data for parts of the analyses where their inclusion would affect item correlations (factor analyses). Statistical analyses were performed using STATA software version 14.0 [106].

2.9.4. Acceptability

Acceptability of the new measure, and a further assessment of content validity, was examined by exploring its use as both a patient- and observer - completed tool.

Acceptability was explored in three ways, by examining:

- response rates
- answers to debriefing questions
- missing data

Response rates for completing the SSI measure

Patient-completed assessments (self-assessments)

Participants were asked to complete the measure to provide a self-assessment of their wound after they had left hospital. Participants were posted a paper-copy of the measure (named as the Wound Healing Questionnaire; WHQ) (Appendix 13) in time for completion around 30 days after their surgery, a widely accepted timeframe for expecting SSI to have occurred [32]. Instructions asked participants to complete the questionnaire in relation to what had happened since leaving hospital after having surgery, in order to collect all relevant information about wound healing since hospital discharge.

Healthcare professional (observer)-completed assessments

Healthcare professionals were asked to complete the measure when performing a participant wound assessment. Data collection for observer-completed assessments was slightly different in the cohort study and the pilot

RCT. In the cohort study, a research nurse or trainee surgeon (involved in the wider Bluebelle study) trained in performing wound assessments attempted to telephone the participant approximately 30-35 days after surgery to discuss how their wound had been healing and any wound care interventions that may have occurred. The nurse or trainee completed the SSI measure (observer assessment) by telephone. Telephone follow-ups were selected for the study design rather than face-to-face follow-up appointments for the entire cohort due to limited financial and staff resources. Any participants who were still in hospital or had returned to hospital at this time-point were, however, seen in person and the SSI measure was completed face-to-face.

In the pilot RCT, all observer assessments were completed by research nurse or surgical trainee as part of a face-to-face appointment with participants between four and eight weeks after surgery. These appointments were part of the trial follow-up for the pilot RCT; telephone follow-ups were not part of the pilot RCT design.

Response rates for completing the SSI outcome measure were examined. Specifically, these included:

i) the number of participant-completed self-assessments;

ii) the number of observer-completed assessments;

iii) the number of participants with either a participant-completed self-assessment or an observer-completed assessment

Demographics and operative details of participants who completed a self-assessment were compared with those who did not have any assessments available at all (that is, neither a participant-completed assessment or an

observer-completed assessment; complete non-responders). This comparison was performed to examine whether there was any observable difference between the groups that might provide an indication of acceptability of the measure for different types of patients.

Debriefing questionnaire

Acceptability was further evaluated by examining answers to debriefing questions. Asking participants to complete an accompanying debriefing questionnaire when field-testing a new outcome measure can provide valuable feedback, collecting information on the feasibility, suitability and content validity (how items are interpreted) so that problems with any of the items can be identified and modified if necessary [46].

In the cohort study only, participants were posted a short debriefing questionnaire along with the new outcome measure to collect data about the feasibility of completing the measure. The debriefing questionnaire included questions on how long it took to complete the outcome measure and whether there were any problems with completing any of the items (Appendix 14). Debriefing questionnaires were administered only to participants (and not to healthcare professionals completing the measure as an observer assessment). This was due to the specific interest in using the measure primarily as a post-discharge patient-reported tool for assessing SSI in future applications of its use. Debriefing questionnaires were only administered to participants in the cohort study (and not the pilot RCT). The cohort study was specifically designed to evaluate the new SSI measure and participants were not being randomised to any wound dressing interventions. There was scope within the study data collection, therefore, to further examine acceptability through the

inclusion of a debriefing questionnaire without the risk of over burdening the participants [88]. The pilot RCT was designed to assess the feasibility of conducting a large RCT of different wound dressing strategies and it was considered that asking participants to complete a debriefing questionnaire alongside the collection of other data necessary for the wider Bluebelle study may over burden participants unnecessarily.

Descriptive statistics were used to summarise the time taken to complete the measure, whether help was needed to answer any items and if participants had difficulty answering any items as reported in the debriefing questionnaire. Additional free text responses from the box provided were examined and summarised to explore problems with feasibility and practicality on answering any of the items or completing the self-assessment.

Missing data

Examination of missing data is a useful method to explore acceptability, suggesting difficulty or problems with items that many not be easy to understand or answer and is a common technique used in the development of outcome measures [46,48]. Patterns in missing responses (that are not occurring at random) can indicate: 1) not understanding the item; 2) that the item was not applicable; 3) that the answers do not fit the response categories; 4) that the responder does not know the answer or does not want to say; or 5) loss of concentration or motivation [46]. Proportion of missing data for each item was examined, in otherwise completed questionnaires. Less than 3% of missing data for each item is considered acceptable, and more than 15% is considered not acceptable [46]. Reasons for missing data were explored by examining any available free text and explanation provided by participants in the debriefing questionnaire.

2.9.5. Reliability

Test-retest reliability

It is important to test whether a new outcome measure demonstrates consistency, stability and reproducibility in the data that it provides [107]. This is to ensure that data are reliable and that a participant would give the same response if they were to complete the measure twice over a period when the condition being measured would not be expected to change. This is called test-retest reliability [46]. To examine this measurement property for the SSI measure, a subset of participants (n=50) in the cohort study were posted a second copy of the measure within one week of completing and returning the first self-assessment. An interval of one week was considered a reasonable timeframe for participants to not recall their previous responses (that is, minimise memory bias) so that a more confident assessment of consistency of responses could be examined [45]. It is a recommended period for test-retest reliability assessments for health measurement instruments [85,108]. Sampling for the test-retest subset of participants was conducted by convenience. During one month of the study, participants who had returned their first self-assessment within the expected timeframe were selected.

It was necessary to determine an 'anchor' question to ensure that participant's health had not changed during the test-retest time period. Item 11 ("Have you been back into hospital for treatment of a problem with your wound?") was used as this anchor question. Responses to the item and any free text comments were examined as an indication of stable health between these assessments.

Agreement in responses is a commonly used and established method to examine reliability [46]. Agreement between test-retest assessments were examined using cross-tabulations of responses. Level of agreement was

calculated using weighted Kappa statistics, typically used for ordinal data [46]. Equal weights between response categories for categorical items (items 1-8) were assumed (because categories were chosen with intended similar increments of severity between each category), with assigned weightings of 0, 0.333, 0.667 and 1 between categories. Kappa values <0.4 were considered poor agreement. Values between 0.4 and 0.75 were considered as fair to good agreement [46]. The stability of participants' responses between test and retest assessment for items with a four-category response option (that is, those assessing signs and symptoms) was also examined using a graphical interpretation. Proportions of participants with an identical response, or those moving between categories, were examined using graphs of the differences in scores between assessments.

Comparison of responses between self- and observer assessments

It was important to examine the reliability of the new outcome measure as a patient-reported tool (PROM). This was in order to assess its suitability for use in research and clinical practice, where effective and efficient patient-reported tools for use post-discharge are lacking. To study this, a comparison of responses in participants self- and observer assessments was examined for participants with available data from both assessments. A comparison of responses for each item was examined using graphical representations. Cross-tabulations of responses from self- and observer assessments for each item and percentages of agreement and discordance between respondents were explored. Level of agreement was calculated using weighted Kappa statistics as described above, with equal weights between response categories for items 1-8. The same cut off values described above for poor, fair and good agreements were applied [46].

2.9.6. Construct validity

Evaluation of a new measure should include an examination of construct validity; 'the degree to which the scores of a measurement instrument are consistent with a hypotheses (for instance with regard to internal relationships, relationships to scores of other instruments, or differences between relevant groups) based on the assumption that the instrument validly measures the construct to be measured' [88]. One way this can be explored is by using a quantitative approach that looks at the underlying structure of the data and how the items correlate or cluster together [46]. This can provide an idea of the dimensionality of the data (that is, its scale structure), and whether the measure may be assessing a single, unidimensional construct or multiple constructs [46].

Determining the scale structure of the measure

The conceptual framework for the SSI measure was based on a reflective model as described earlier (section 2.7). It is appropriate to analyse a reflective model using the principles of classical test theory (CTT). This is a measurement theory based on the principal of measuring an unobservable construct indirectly through the measurement of observable characteristics that are manifestations of that construct [46]. Classical test theory has been widely applied to assess outcome measures based on a reflective model conceptual framework, with multi-trait scaling and factor analysis being suitable analytic methods [46].

In this study, analyses explored whether items in the new measure were reflective of an underlying unidimensional 'SSI' construct or whether items

reflected a more complex multi-dimensional construct. This was performed to determine what the data was suggesting about the structure of the measure, and whether it was appropriate to analyse the responses as one single scale or if a set of multiple scales were more appropriate. Findings, therefore, would have implications for how to score the responses and determine a scoring system, important for further use of the measure in practice. Two methodological techniques were employed for this purpose; multi-trait scaling and factor analysis. Both techniques are used for the analysis of patient-reported health status data such as symptoms and quality of life, and either are sufficient and appropriate [86]. For methodological interest and for the purpose of applying a comparative statistical approach, both multi-trait scaling and factor analysis were used in this study. Multi-trait scaling was chosen as the primary method for analysis and exploratory factor analysis (EFA) was performed as a secondary 'sensitivity' analysis. Details and reasons for this approach are described in the paragraphs below.

Sample size for assessing construct validity

There are no general rules for calculating a sample size for performing statistical tests on the structure of the data, and requirements will vary depending on factors such as the number of items and the distribution of responses (which is difficult to know in advance). Sample sizes have been based on a "rule of thumb" commonly described in the literature. It is estimated that an appropriate sample sizes should be at least five to seven, or 10 times the number of items, with a minimum sample of 100 recommended [86,109]. Analysis of scale structure in the current study was initially conducted with data from the cohort study, which had a sample size that was more than sufficient to meet these approximate rules. The best fitting model

was then applied to data from the pilot RCT, to serve as a method of independent validation of the scale structure.

Initial examination of item correlations

Observations of very high correlations (>0.9) can suggest that items may be very similar or overlapping and can inform decisions on whether items may be redundant and removed before conducting further analyses of the scale structure [46]. Before conducting multi-trait scaling or factor analyses, correlations of all pairs of items and additional questions were first explored in data from the cohort study using Pearson's correlation coefficient (Pearson's r). Item-item correlations of 0.9 or above were examined for similarity and therefore possible redundancy and exclusion in subsequent analysis of the underlying structure of the measure [46].

Multi-trait scaling analysis

Multi-trait scaling analysis to examine the underlying structure of an outcome measure can be used when there is a hypothesised structure for the data [84]. It is a relatively simple technique that has been used extensively for evaluating health status measures that aim to assess underlying health domains or 'traits' [86]. Multi-trait scaling is based on an examination of estimated Cronbach's alpha coefficients for items within a hypothesised scale structure; that is, the underlying domain or set of domains ('multiple traits') that the measure is intended to assess. Co-efficients are drawn up in a correlation matrix for items within the hypothesised scales (item-scale correlations). Correlations must be corrected for overlap (of the item in the item-trait relationship) so estimates of a relationship are not inflated [84]. Each row in the matrix contains correlations between responses ('scores') for

one item and all of the hypothesised scales (defined by the sum of items comprising each scale). Each column contains correlations between the scores for one scale and all the individual items in the analysis [84].

Multi-trait scaling works on the principles of convergent and discriminant validity. Convergent validity refers to the extent that items within a scale correlate with each other. Discriminant validity refers to demonstrating that items from another scale do not correlate well with items from a different scale [84]. Evidence of discriminant validity suggests that items in different scales are unrelated, demonstrating that separate scales to measure the underlying construct is appropriate [86]. Multi-trait scaling is simpler that other statistical techniques employed to examine the dimensionality of the data, such as factor analysis, however it is considered to be adequate and sufficient for analysing symptoms and health-related quality of life data [84].

Multi-trait scaling was selected as appropriate, therefore, as a primary method for evaluating the underlying structure of the SSI measure because of its suitability for use in the measurement of symptoms and health-related quality of life issues. It was planned to explore hypothesised scales in advance. Two *a priori* hypotheses for the scale structure of the new measure were proposed by the study team, based on expert opinion and knowledge of the condition. The first was a unidimensional construct for 'SSI', hypothesising that all items correlate together to measure SSI in a single scale. The second was a proposed more complex hypothesised multi-dimensional construct for SSI, informed by clinical experience and knowledge of the literature within the study team of how signs, symptoms and interventions may occur together. The conceptual multi-dimensional construct consisted of four multi-item scales and two single items (Table 2-2).

Table 2-2. Hypothesised multi-dimensional conceptual structure of the SSI measure, consisting of four multi-item scales and two single items

Hypothesised scale / single item	Number of items in scale	Item
Inflammation	4	1. Was there redness spreading away from the wound? (erythema/cellulitis) 2. Was the area around the wound warmer than the surrounding skin? 5. Has the area around the wound become swollen? 7. Has the wound been painful to touch?
Wound leaking	5	3. Was any part of the wound leaking fluid? 3a. Was it clear fluid? (serous exudate) 3b. Was it blood-stained fluid? (haemoserous exudate) 3c. Was it thick and yellow/green fluid? (pus/purulent exudate) 10. Has anything been put on the skin to cover the wound?
Dehiscence	3	4. Have the edges of any part of the wound separated/gaped open on their own accord? (spontaneous dehiscence) 4a. Did the skin separate? 4b. Did the deeper tissue separate?
Wound care interventions	7	9. Have you sought advice because of a problem with your wound, other than at a planned follow-up appointment? 12. Have you been given antibiotics for a problem with your wound? 11. Have you been back into hospital for treatment of a problem with your wound? 13. Have the edges of your wound been deliberately separated by a doctor or nurse? 14. Has your wound been scraped or cut to remove any unwanted tissue? (debridement of wound) 15. Has your wound been drained? (drainage of pus / abscess) 16. Have you had an operation under general anaesthetic for treatment of a problem with your wound?
Smell	1	6. Has the wound been smelly?
Fever	1	8. Have you had, or felt like you have had, a raised temperature or fever? (fever <38^{o}C)

Performing the multi-trait scaling analyses

First, a simple model with one single scale was tested with data from the cohort study. Analyses were performed separately for participant self-reported and observer data for methodological interest to compare the fit of the model when the measure was used as a PROM or an observer-completed tool. Item-scale correlations for a single scale were examined. Next, a more complex model to reflect the hypothesised multi-dimensional scale structure was tested. Item-scale correlations were examined for convergent and discriminant validity, the established method for testing the fit if the data to the model, as described. Item convergence was supported if an item correlated substantially (correlations of 0.30 or higher) with the hypothesised scale (examined in matrix columns). Item discrimination was supported if the highest correlation (examined in matrix rows) was between the item and its own hypothesised scale, compared with other scales in the model [84].

Factor analysis

Factor analysis is an alternative statistical approach to examine the structure of the data in the development of a new outcome measure [46,84]. Factor analysis can be distinguished as exploratory factor analysis (EFA) and confirmatory factor analysis (CFA). Exploratory factor analysis is performed when there is no strong *a priori* theoretical or conceptual expectation of the number or type of factors. As the name suggests it is an exploratory technique and is suitable for use early on during the development of a new measurement instrument. Confirmatory factor analysis is more suitable when there is a defined or hypothesised scale structure and more common for the validation of a new measurement instrument. In CFA, a model is tested to see if the data fits the hypothesised model, similar to the principals of multi-trait

scaling. Factor analysis originates from the field of education although has widely been adopted in psychology and for psychometric testing of measurement instruments including quality of life and symptom questionnaires [46,86].

Exploratory factor analysis was used as second statistical approach to evaluate the underlying structure of the SSI measure for two reasons. First, to explore whether items clustered together in a way that had not been hypothesised *a priori* and therefore could not be tested using multi-trait scaling, and second, as a 'sensitivity analysis' to examine the differences between multi-trait scaling and factor analysis for exploring the dimensionality of the data for methodological interest.

There are several assumptions and choices when using factor analysis. One is the appropriateness of the dataset. Traditionally, factor analysis is regarded as a method more suitable for continuous data with a normal distribution. The response options in the new measure meant that data were ordinal categorical data. A technique has been developed to allow factor analysis to be applied to data where the assumption of a normal distribution is not met (e.g. skewed data). This uses a polychoric matrix rather than a correlation matrix to apply the factor analysis [86,110]. Another choice in factor analysis is the method of estimation that can be used for selecting a model, with several methods available [84]. This study chose maximum-likelihood (ml), recommended as a suitable method to use that is robust when data do not meet all the assumptions [86]. Following analysis, researchers also have the choice to perform 'rotation' to the factor structure to aid interpretation. Rotation shuffles the items and their loadings to each factor without changing the

number of factors. It aims to load items more on to one factor without changing the number of factors in the model. Whichever method and choices are made in factor analysis, interpretation of the model and the factors must always be clinically meaningful [86].

Performing the exploratory factor analyses

Factor analyses were performed to explore possible data structures using data from the cohort study, separately for patient and observer data. Analyses were run specifying the maximum number of factors to be retained as one, two and three factors, in three separate models and in that order. The single factor model was used as a comparator for the single scale model in the multi-trait scaling analyses. The two and three factor models were used to examine whether the items clustered together in a set of multi-item scales in a different way to that hypothesised (Table 2-2) by examining the item factor loadings on to each factor. The suitability of the one, two and three factor models was explored by examining and comparing eigenvalues [86].

Validation of the scale structure

The most suitable model fitting data from the cohort study was examined for replicability of good fit using data from the pilot RCT (as a method of independent validation for the scale structure, described above). The model was finally applied to the combined data (cohort study and pilot RCT data together) to examine the parameters when applied to the entire dataset.

Sensitivity analysis: factor analysis with a polychoric matrix

Response options to the items in the measure were categorical (not at all, a little, quite a bit, a lot) or binary (yes, no) meaning that data were ordinal or dichotomous. Standard methods for factor analysis assume that data are continuous and follow a normal distribution. As a sensitivity analysis, therefore, and to account for any skewed distribution of the data, factor analysis using a polychoric matrix was applied and compared with the traditional correlation matrix [110,111]. Combined data from the cohort and pilot RCT were used.

Internal consistency of the scales

Internal consistency is a measure of the extent to which items in a scale assess the same construct [46]. It is defined as the degree of relatedness among the items in a scale [88]. Internal consistency can be assessed by Cronbach alpha coefficient. As part of the evaluation of the scale structure of the new measure, internal consistency for the scales in the derived structure (determined from the multi-trait scaling and EFA) were examined using Cronbach alpha coefficients. Values greater than 0.7 were considered to have good internal consistency, in line with thresholds used in the literature[46].

2.9.7. Criterion validity

Criterion validity is defined as 'the degree to which the scores of a measurement instrument are an adequate reflection of a gold standard' [88]. When a reference standard for measuring the construct of interest exists, this allows for an assessment of how well the new measure performs compared to the existing reference standard. Criterion validity is essential for outcome

measures designed for use as diagnostic tests for a condition or disease [46]. It was a measurement property that was, therefore, important to consider in the context of SSI.

Sensitivity and specificity for SSI diagnoses

A key objective in the current study was to explore the ability of the new measure to correctly classify individuals as having SSI or no SSI. This can be assessed by two parameters, sensitivity and specificity. Sensitivity can be described as the proportion of true positives correctly identified as positive [112]. In the context of the current study, that translates to the proportion of participants correctly identified as having SSI. Specificity can be described as the proportion of true negatives correctly identified as negative [112]. In the context of the current study that translates to the proportion of participants correctly identified as not having SSI. To estimate the parameters of sensitivity and specificity, each individual needs to be classified using a 'gold-standard' or reference assessment.

Reference SSI assessments

In the current study, a face-to-face assessment of whether SSI had occurred since the time of surgery using the CDC criteria and definition was used as the reference standard for comparison with the new measure [32]. As described in Chapter 1, the CDC definition is the most commonly used definition for SSI in practice and is widely accepted as the best definition currently available [11,44]. It was, therefore, selected as the most suitable reference standard for the current study.

Participants were invited to attend for a face-to-face study appointment between four and eight weeks after surgery. In the cohort study, an opportunistic subset of patients was invited, aiming for 25% of the cohort due to limitations of study resources (staff and room availability, and costs). Participants for the face-to-face assessment were sampled by convenience and to maximise the number of possible SSIs in the sample, by inviting patients that reported problems with wound healing during the telephone follow-up. Appointments were arranged to coincide with a routine hospital visit if possible. In the pilot RCT, all participants were invited to attend for a face-to-face follow-up assessment as part of the study design.

Reference assessments were performed at the face-to-face appointment by a clinical member (for example, a surgeon, surgical trainee or research nurse trained in assessing wounds for SSI) of the Bluebelle study team, blinded to the responses on the patient-completed measure (self-assessment) and observer-completed measure (telephone assessment), where possible. The clinical assessor checked through each CDC criteria using information from the patient, hospital records or any other available information and indicated on a study data collection form whether any of the criteria had been met since the time of surgery. The criteria were then used to give a diagnosis of: i) none; ii) superficial; iii) deep, or; iv) organ/space SSI using the CDC classification [32].

Receiver operating characteristic (ROC) curve

Methods to examine criterion validity, and the strength of the relationship between a new measure and a reference standard, depend on the level of measurement (that is, the type of data) of the two measure. Appropriate and

common methods when the new measure has a continuous or ordinal scale and the reference standard is dichotomous (that is, condition/disease or no condition/disease), as is the case for the current study, are to use sensitivity and specificity parameters to plot a receiver operating characteristic (ROC) curve [46]. A ROC curve is a plot of sensitivity against 1-specificity for different levels of cut-off in the continuous/ordinal score of the new measure [112].

Patient self-assessment was used to calculate sensitivity and specificity parameters of the new measure. Self-assessment data were used rather than observer assessment data due to the interest in the criterion validity of the measure for potential use as a post-discharge patient-reported tool for assessing SSI in future applications.

Plotting the ROC curve

Plotting the ROC curve was done through a series of steps:

i) Participants' self-assessment total score on the new measure was calculated. An appropriate scoring system to calculate the total score was informed by findings from the analysis of the scale structure (methods described earlier in this chapter). Data from participants' reference SSI assessment (from the face-to-face appointment using the CDC criteria) were used to create a dichotomous variable of 'no SSI' or 'SSI of any type'.

ii) A cross-tabulation of frequencies of participants' total score against the reference SSI assessment was examined to compare the total scores on the new measure with the reference diagnoses for SSI.

iii) Data were subsequently used to calculate sensitivity and specificity values for different levels of cut off score on the new measure using the following formulae:

$$\text{sensitivity} = \frac{\text{number of true positives}}{\text{number of true positives} + \text{number of false negatives}}$$

$$\text{specificity} = \frac{\text{number of true negatives}}{\text{number of true negatives} + \text{number of false positives}}$$

iv) All values of sensitivity against 1- specificity were used to plot a ROC curve.

The area under the curve and 95% confidence intervals were examined to assess how well the new measure correctly classified individuals as having had an SSI and not having had SSI against the reference assessment. An AUC values approaching 1.0 indicates high sensitivity and specificity, that is, good discrimination, whereas a value of 0.5 indicates no ability to discriminate at all [112].

Interpretation of criterion validity in the absence of a perfect reference standard

Often in practice, a true 'gold' standard diagnostic test does not exist. There may be known limitations to the existing tool, for example, or there may be differences between the measured value and the true value (measurement error) [113]. Several options are available for evaluating the diagnostic accuracy of a new test when there is no gold standard or if the gold standard

is imperfect. Examples include validation of the reference standard with future clinical events (if these are relevant and available), or using statistical methods to correct for the degree of imperfection of the reference standard [113]. In the current study a face-to-face SSI diagnosis determined from using the CDC criteria was used as the reference standard for comparison with the new measure. While the CDC definition and criteria are widely accepted and commonly used to diagnose SSI [11], there are known limitations regarding its subjectivity and problems with measurement, as detailed in the introductory chapter of this thesis (Chapter 1) [11]. The use of statistical methods to correct for this 'imperfect' reference standard was not, however, possible, as there is no reliable information on the degree of imperfection of CDC diagnoses in the field of SSI measurement. Sensitivity and specificity of the new SSI measure against the CDC reference standard, therefore, were made with consideration of these known limitations. This limitation is returned to in the Discussion chapter of this thesis (Chapter 6).

Justification for no further tests for validity

As described in the introduction to this chapter, construct validity can be broken down into three types: structural validity, hypotheses-testing and cross-cultural validity. The current analysis focused on examining structural validity of the new measure. While methods for hypothesis testing (for example, 'known-group' comparisons) and cross-cultural validity exist [46,86], these were considered to be outside the scope of the current study. Reasons for this are described below.

Hypothesis testing using known-group comparisons

A valuable test for construct validity of a new measurement instrument can be to examine the ability of the measure to discriminate between 'known-groups' where you would expect there to be a difference between scores or performance on the new measure. Indeed, construct validity has been defined as 'the degree to which the scores of a measurement instrument are consistent with hypotheses' [88]. In the current study in abdominal surgery, aside from SSI diagnosis, there was no hypothesised grouping of patients where a difference in scores on the new measure may be expected, using clinical criteria that could reliably and accurately be collected as part of the study. Known-group comparison was, however, in part addressed by the ROC curve analysis where the self-assessment total score was compared for those diagnosed with and without an SSI, using the reference SSI assessment. Statistical tests to compare of mean scores in the new measure for participants grouped by SSI diagnosis were, therefore, considered to be unnecessary. In the absence of other known groups for which expected differences in scores in the new measure may be hypothesised, no other group comparisons were conducted.

Cross-cultural validity

Examination of cross-cultural validation would require translated or culturally adapted versions of the measure. A study of cross-cultural validity would be suitable for future studies with resources to do so. This is an area for further work that is being considered and is returned to in the Discussion chapter of this thesis (Chapter 6).

2.9.8. Modifications to produce the final measure

Common practice in the development of outcome measures is to use field-testing studies to inform any final necessary modifications to the measure, including the need to modify or drop any items from the measure completely [46,85,86]. Findings from Phase 4 of the current study were, therefore, used to inform a final round of modifications to produce a final version of the new SSI measure. Evidence on how the items were performing was evaluated on an item-by-item basis by using data from the debriefing questionnaire, missing data, test-retest reliability, patient and HCP agreement and scaling structure. Potentially problematic or seemingly redundant items were discussed with the study team (experts in the development and validation of outcome measures and experts in SSI assessment) and final decisions on whether to drop any items were made through discussion. The clinical relevance of items was paramount to any decisions on whether items should be dropped from the outcome measure. The following chapter will describe the results of all the analyses described here, concluding with the final version of the measure ready for use in trials and clinical practice.

2.9.9. Summary

This chapter has described in detail the methods for the development and validation of a new outcome measure for SSI. It describes how the essential properties of an outcome measure were addressed in the study, including content, construct and criterion validity, reliability and acceptability. Robust, established methodology was used to ensure these properties were addressed, with a particular emphasis on a novel 'universal-reporter' design to the outcome measure (UROM), suitable for patient and/or healthcare

professional completion. The chapter describes the methods applied in four chronological phases of the study: 1) a content analysis and semi-structured interviews with key stakeholders to identify content domains; 2) design of the outcome measure including item formulation, response categories and instructions for completion; 3) cognitive interviews with patients and healthcare professionals to pre-test the preliminary measure; and 4) field-testing the measure in a large sample of patients following surgery. Throughout the chapter, the theory and rationale for using the applied methods are described. The next chapter will now describe the findings from this study.

CHAPTER 3. RESULTS: STUDY 1

DEVELOPMENT AND VALIDATION OF A NEW OUTCOME MEASURE FOR SSI

3.1. Introduction

This chapter describes the results of the development and validation of a new outcome measure for surgical site infection, for patient or healthcare professional completion. The chapter is structured to mirror the methods described in the previous chapter. It concludes with a brief discussion, including of the strengths and limitations of this study.

An overview of each of the study phases, and the essential property of the new outcome measure being addressed during its development and validation, are provided as a reminder in Table 3-1. The datasets and final sample size in each study are also included.

Table 3-1. Overview of the study phases, methods and datasets included in the development and validation of the SSI outcome measure

Essential property	Study phase	Method	Dataset / sample size
Content validity Acceptability	Phase 1: Identification of important domains	(i) Analysis of existing SSI assessment tools (ii) Interviews with patients and healthcare professionals	n=4 tools n=19 participants
	Phase 2: Designing the outcome measure	Item formulation	n/a
	Phase 3: Pre-testing	Cognitive interviews	n=42 participants
Construct validity Criterion validity Reliability Acceptability	Phase 4: Field-testing	Analysis of data from a cohort study and pilot RCT	n=792 participants

3.2. Phase 1 - Identification of important domains: content validity

3.2.1. Content analysis of existing SSI tools

Identification of existing SSI assessment tools

The existing systematic review published by Bruce et al. in 2001 [11,31] identified the most commonly used definitions and grading scales for defining and diagnosing SSI. Two (one definition and one grading scale) were found to be most commonly used. These were the CDC definition and the ASEPSIS grading scale [32,51]. The scoping review performed as part of the current study confirmed these were still the most common tools for SSI assessment used in current practice.

CDC criteria and associated tools

As described in Chapter 1, when the CDC definition has been employed in practice, there are examples where the diagnostic criteria in written definition have been converted into a 'checklist' tool for healthcare professionals to complete to aid data collection and diagnosis. Checklists of criteria as tools to aid SSI diagnosis were described in detail in Chapter 1.

A longstanding and widely used example of a checklist tool based on the CDC criteria was known to the study team. This was the tool used by the PHE SSISS programme, described in Chapter 1 [34]. The PHE SSISS surveillance data collection forms include a list of SSI criteria with an adjacent box to be ticked if that criterion is met (Appendix 15). The tool is intended for designated surveillance staff within the hospital to complete. The PHE SSISS tool was selected as an appropriate exemplar of a CDC checklist tool to include in the content analysis for the current study due to its wide and standard use.

In addition to the checklist for surveillance staff completion, the PHE SSISS also uses an optional post-discharge questionnaire for patients to complete within 30 days following surgery. The questionnaire is also based on the CDC criteria for SSI and includes 12 questions (items) to collect information about relevant symptoms and wound management (Appendix 4). Data from the questionnaire are used to supplement other data collected from hospital records as a method for identifying SSI that develop post-discharge. As previously described in Chapter 1, the questionnaire is not intended as a patient-reported outcome measure for SSI and has not undergone any formal development or validation. The items are, however, based on some of the CDC criteria therefore it was considered a relevant tool for including in the content analysis to inform the development of the new outcome measure in the current study.

ASEPSIS tools

As described in Chapter 1, the ASEPSIS grading scale was developed for use in hospital, for completion by a healthcare professional. The tool includes a list of wound characteristics considered to be important for defining SSI. These are serous exudate, erythema, purulent exudate and separation of deep tissue. A 'points' grading system is used, assigning points based on the proportion of the wound affected [51]. Further objective criteria are assessed, and more points added if the criteria are met, including antibiotic administration, drainage of pus, debridement, microbiology results and extended hospital stay (Appendix 16). Points are combined to give an overall score.

An associated patient questionnaire has since been designed by authors of the ASEPSIS scale. [57,58]. Intended for completion by patients after leaving hospital, the questionnaire has been used to determine SSI in conjunction with data collected in hospital using the clinical tool [57,114]. The questionnaire for patients consists of 10 questions, derived from the wound characteristics and criteria in the grading scale, with conditional yes/no response options (Appendix 5). Whilst the questionnaire did not have patient input in its development and has not been formally validated, it has been used as a post-discharge questionnaire to collect SSI data from patients in research studies [57,114]. It was, therefore, considered a relevant tool to inform the development of the new outcome measure in the current study and was included as a data source for the content analysis.

Source documents

A total of four source documents, therefore, were identified and obtained for the content analysis of existing tools: i) the PHE SSISS checklist of SSI criteria based on the CDC definition, ii) the PHE SSISS post-discharge patient questionnaire, iii) the ASEPSIS grading scale, and, iv) the ASEPSIS-associated patient questionnaire. Table 3-2 summarises these source documents. At the time of conducting the current study, current version of the PHE SSISS checklist and post-discharge questionnaire were obtained from the PHE surveillance protocol, available online [34]. The ASEPSIS grading scale and associated patient questionnaire were obtained from published literature [51,57].

Table 3-2. Overview of source documents used to identify important SSI domains

Source document	Designed for completion by	Number of included criteria/items	Response categories
PHE SSISS checklist	HCP	11	Tick boxes
PHE SSISS PQ	Patient	12	Tick boxes; yes/no options
ASEPSIS grading scale	HCP	9	Numerical score based on presence; proportion of wound affected
ASEPSIS-associated PQ	Patient	10	Yes/no options

PHE SSISS: Public Health England Surgical Site Infection Surveillance Service; PQ: patient questionnaire; HCP: healthcare professional

Data extraction

Verbatim text was extracted from the source documents. These included:

i) specific checklist criteria from the PHE SSISS data collection form;

ii) items from the PHE SSISS post-discharge questionnaire for patients;

iii) wound characteristics and objective criteria listed in the ASEPSIS grading scale;

iv) items from the ASEPSIS-associated patient questionnaire

A total of 42 verbatim criteria and items, and their response categories, were extracted (Table 3-3).

Table 3-3. Individual criteria, items and response categories extracted from existing SSI tools

Existing tool		Criteria / item	Response option
PHE checklist	1	Abscess or other evidence of infection found during a re-operation, by radiology or histopath examination	Tick box
	2	Antibiotics prescribed by GP for SSI (patient reported only)	Tick box
	3	Aspirated fluid/swab of surgical site yields organisms and pus cells are present	Tick box
	4	Fever (temperature 38^{o}C or more)	Tick box
	5	Heat	Tick box
	6	Incision spontaneously dehisces or opened by surgeon	Tick box
	7	Clinician's diagnosis	Tick box
	8	Localised pain and tenderness	Tick box
	9	Localised swelling	Tick box
	10	Purulent drainage	Tick box
	11	Redness	Tick box
PHE PQ	12	Have you had any problems with the healing of your wound?	Yes / No
	13	Was there any discharge or leakage of fluid from any part of the wound?	Yes / No
	14	If yes, was it either Clear or blood stained Yellow/green (pus) Other – please specify	Tick box
	15	Pain or soreness in addition to the discomfort experienced following the operation	Tick box
	16	Redness or inflammation spreading from the edges of the wound	Tick box
	17	The area around the wound felt warmer/hotter than the surrounding skin	Tick box
	18	The area around the wound became swollen	Tick box
	19	The edges of any part of the wound separated or gaped open	Tick box

Existing tool	Criteria / item		Response option
	20	Did any health care worker take a sample from your wound to send to the laboratory?	Yes / No
	21	If you saw a health care worker because of these symptoms, please indicate who you saw from the list (GP/district nurse/midwife/doctor or nurse at the hospital/other - please specify)	Tick box
	22	Have you been prescribed antibiotics for an infection in the wound? [If yes, who prescribed them? ___]	Yes / No
	23	Have you been re-admitted to hospital with an infection of the surgical wound? To the hospital at which the operation was carried out? To another hospital? [If yes, which one? _____]	Yes / No
ASEPSIS scale	24	Serous discharge/exudate	% of wound affected
	25	Erythema	% of wound affected
	26	Purulent exudate	% of wound affected
	27	Separation of deep tissues	% of wound affected
	28	Antibiotics	Unspecified*
	29	Drainage of pus under local anaesthesia	Unspecified*
	30	Debridement of wound (general anaesthesia)	Unspecified*
	31	Isolation of bacteria	Unspecified*
	32	Stay as inpatient prolonged over 14 days	Unspecified*
ASEPSIS-associated PQ	33	Have the wounds healed without any problem at all?	Yes / No
	34	Has the wound been red?	Yes / No
	35	Has the wound discharged clear yellow fluid?	Yes / No
	36	Has the wound discharged pus?	Yes / No
	37	Has the wound broken open?	Yes / No

Existing tool	Criteria / item	Response option
	38 Have you been given antibiotics for wound infection?	Yes / No
	39 Has a district nurse had to dress the wound?	Yes / No
	40 Has a doctor opened/drained an abscess?	Yes / No
	41 Have you been admitted to hospital elsewhere?	Yes / No
	42 Has the wound been opened and cleaned under general anaesthetic in hospital?	Yes / No

*original publication does not detail a response option; however, criteria require a dichotomous response (either yes/no or tick box)

PHE: Public Health England; PQ: patient questionnaire; GP: General practitioner; SSI: Surgical site infection

Categorisation into SSI domains

Extracted criteria and items were categorised into SSI domains, defined as broad aspects of the effect of SSI on the patient, as described in Chapter 2. One criterion, "clinician's diagnosis" (extracted from the PHE SSISS), was excluded. The subjectivity of this criterion is recognised as a problem in existing literature [37,38,53]. It was considered by the study team to be too broad and unspecific to be useful for inclusion in the new outcome measure. In total, the 42 criteria/items were categorised into 18 domains: eight domains related to the signs or symptoms indicative of SSI (for example, 'wound redness' and 'wound pain') and 10 domains related to SSI interventions and investigations (for example, 'drainage needed' (Table 3-4).

Table 3-4. Categorisation of criteria and items from existing tools into SSI domains

SSI Domain		Criteria / item from existing tool	Source (existing tool)
1	Wound healing	• Have you had any problems with the healing of your wound?	PHE PQ
		• Have all of these wounds healed without any problem at all?	ASEPSIS-associated PQ
2	Wound heat	• The area around the wound felt warmer/hotter than the surrounding skin	PHE PQ
		• Heat	ASEPSIS-associated PQ
3	Wound redness	• Has the wound been red?	ASEPSIS-associated PQ
		• Redness or inflammation spreading from the edges of the wound	PHE PQ
		• Erythema	ASEPSIS scale
		• Redness	PHE checklist
4	Wound discharge	• Has the wound discharged clear yellow fluid?	ASEPSIS-associated PQ
		• Has the wound discharged pus?	ASEPSIS-associated PQ
		• Purulent drainage	PHE checklist
		• Was there any discharge or leakage of fluid from any part of the wound? If yes, was it either Clear or blood stained Yellow/green (pus) Other	PHE PQ
		• Serous discharge/exudate	ASEPSIS scale
		• Purulent exudate	ASEPSIS scale
5	Layers separating - spontaneous	• Has the wound broken open?	ASEPSIS-associated PQ
		• The edges of any part of the wound separated or gaped open	PHE PQ

SSI Domain		Criteria / item from existing tool	Source (existing tool)
		• Separation of deep tissues	ASEPSIS scale
		• Incision spontaneously dehisces [/opened by surgeon]	PHE checklist
6	Wound swelling	• The area around the wound became swollen	PHE PQ
		• Localised swelling	PHE checklist
7	Wound pain	• Pain or soreness in addition to the discomfort experienced following the operation	PHE PQ
		• Localised pain and tenderness	PHE checklist
8	Fever	• Fever (temperature 38°C or more)	PHE checklist
9	Contact with healthcare professional	• If you saw a health care worker because of these symptoms, please indicate who you saw from the list (GP/district nurse/midwife/doctor or nurse at the hospital/other - please specify)	PHE PQ
10	Dressing needed	• Has a district nurse had to dress the wound?	ASEPSIS-associated PQ
11	Antibiotics needed	• Have you been given antibiotics for wound infection?	ASEPSIS-associated PQ
		• Have you been prescribed antibiotics for an infection in the wound? If yes, who prescribed them?	PHE PQ
		• Antibiotics prescribed	ASEPSIS scale
		• Antibiotics prescribed by GP for SSI (patient reported only)	PHE checklist
12	Layers separating - deliberate	• Incision opened by surgeon [/spontaneously dehisces]	PHE checklist
13	Hospital admission	• Have you been admitted to hospital elsewhere?	ASEPSIS-associated PQ

SSI Domain		Criteria / item from existing tool	Source (existing tool)
		• Have you been re-admitted to hospital with an infection of the surgical wound? To the hospital at which the operation was carried out? To another hospital?	PHE PQ
14	Drainage needed	• Drainage of pus under local anaesthesia (including vac therapy)	ASEPSIS scale
		• Purulent drainage	PHE checklist
15	Wound cleaning	• Has the wound been opened and cleaned under general anaesthetic in hospital?	ASEPSIS-associated PQ
		• Debridement of wound (general anaesthesia)	ASEPSIS scale
		• Purulent drainage	PHE checklist
16	Abscess	• Has a doctor opened/drained an abscess?	ASEPSIS-associated PQ
		• Abscess or other evidence of infection found during a re-operation, by radiology or histopath examination	PHE checklist
17	Microbiology	• Did any health care worker take a sample from your wound to send to the laboratory?	PHE PQ
		• Aspirated fluid/swab of surgical site yields organisms and pus cells are present	PHE checklist
		• Isolation of bacteria	ASEPSIS scale
18	Prolonged hospital stay	• Stay as inpatient prolonged over 14 days	ASEPSIS scale

PHE: Public Health England; PQ: Patient questionnaire; GP: General practitioner; SSI: Surgical site infection

3.2.2. Interviews with patients and healthcare professionals

Participants

Some 28 potential participants (15 patients, 13 healthcare professionals) expressed interest in the study and 19 (67.9%) consented to be interviewed. Reasons for not being interviewed are provided in Figure 3-1. Interviews were conducted with nine patients and 10 healthcare professionals. Participant demographics are shown in Table 3-5.

Figure 3-1. Patients and healthcare professionals approached and recruited for interviews

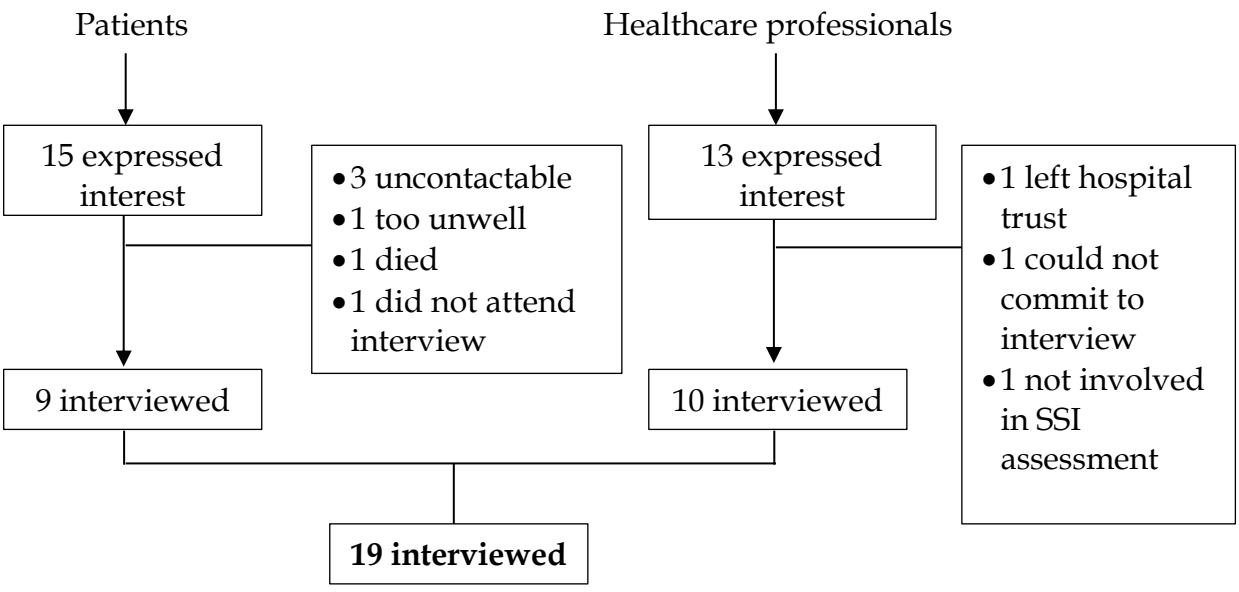


Table 3-5. Participant demographics for Phase 1 interviews: identification of important domains.

		Healthcare professionals (n=10)	Patients (n=9)
Gender	Female	6	4
	Male	4	5
Role	Consultant	5	
	Midwife	1	
	Nurse	1	
	Registrar	3	
Specialty	Obstetrics	4	
	Paediatric	3	
	Stoma care	1	
	Upper GI	2	
Type of surgery	Upper GI benign		2
	Upper GI cancer		1
	Lower GI cancer		1
	Lower GI benign		3
	Appendicectomy		2
Wound infection	Confirmed		2
	Suspected		1
	Absent		2
	Missing data		4

GI: gastrointestinal

Emerging themes relevant to the content for the new outcome measure

The aim of the interview component of this study was to identify a list of themes relevant to the assessment and management of wound for SSI to consider for inclusion in the new outcome measure, as described in the methods (Chapter 2). The findings are presented as a list of these themes. Findings were classified into two overarching themes, organised under the topics guiding the interviews. Broadly, these were i) SSI signs and symptoms, and ii) wound management care and SSI treatment interventions.

SSI signs and symptoms

The following specific themes within the broader category of SSI signs and symptoms were described by participants as being indicative of infection or experienced by patients:

- cellulitis or redness around the wound
- discharge of pus
- tenderness
- pain or soreness of the wound
- breakdown/opening of the wound
- feeling generally unwell, often associated with a temperature or fever
- hot wound
- abscess
- swelling
- raised white blood cell count
- smell

Wound management care and SSI treatment interventions

Specific themes within the broader category of wound management care and interventions identified from interviews as key to the experience of having an SSI or important for its diagnosis/management included:

- prescription of antibiotics
- wound drainage
- dressing changes
- cleaning of wound
- taking swabs
- imaging investigations

Views on existing tools: item wording and response categories

As well as exploring participants' experience of having an SSI or managing patients with SSI to identify relevant content for the new outcome measure, interviews also sought views on the existing PHE and ASEPSIS tools to inform the development of the new outcome measure. Interviews with patients identified some problems with the language used in existing tools. Several words used in items were found to have a lack of understanding of their meaning or had differences in interpretation. These words were "pus", "discharge" and "abscess". In addition, interviews with patients who had experienced a wound infection identified that the word 'infection' was not always used to describe accounts of their experiences. Instead there was a preference for describing wound healing and issues around wound healing.

A further finding from the interviews of relevance to the design of the new outcome measure was the importance of the spectrum of infection. Participants described how signs and symptoms of infection ranged from mild to severe. Participants expressed a need and requirement for a range of response categories, currently not available in the existing clinical and patient tools so that the severity or frequency of some signs/symptoms could be adequately reported.

3.2.3. Synthesis of findings

Findings from the content analysis of existing tools and interviews were combined. It was possible to directly map all the themes relating to signs, symptoms and interventions derived from the interview data onto the list of

18 SSI domains identified from the content analyses of existing tools. The exception was one theme (smell) which was identified from the interview data and not a component of the existing SSI tools. Adding smell to the list of domains, therefore, resulted in a total of 19 different SSI domains to consider for inclusion in the new SSI measure (Table 3-6).

Table 3-6. Identified SSI domains and data source of origin

	Data source		
SSI Domain	Clinical tool(s)	Patient questionnaire(s)	Interviews
1. Wound healing	x	✓	✓
2. Wound heat	✓	✓	✓
3. Wound redness	✓	✓	✓
4. Wound discharge	✓	✓	✓
5. Layers separating – spontaneous	✓	✓	✓
6. Wound swelling	✓	✓	✓
7. Wound pain	✓	✓	✓
8. Fever	✓	x	✓
9. Contact with HCP	x	✓	x
10. Dressing needed	x	✓	✓
11. Antibiotics needed	✓	✓	✓
12. Layers separating - deliberate	✓	x	✓
13. Hospital admission	x	✓	✓
14. Drainage needed	✓	x	✓
15. Wound cleaning	✓	✓	✓
16. Abscess	✓	✓	✓
17. Microbiology	✓	✓	✓
18. Prolonged hospital stay	✓	x	x
19. Smell	x	x	✓

HCP: healthcare professional

3.3. Phase 2 - Designing the preliminary measure: content and face validity

3.3.1. Operationalisation of domains into items: a novel approach combining plain language and medical terminology

All 19 SSI domains identified in Phase 1 were initially considered for inclusion in the new measure. There were two domains that were, however, subsequently deemed not suitable for a measure that was intended for patient completion. These were microbiology and prolonged hospital stay (domains 17 and 18). The study team considered that it was unlikely that information regarding microbiology could be reliably reported by a patient, if indeed information was even known. Similarly, it was considered that patients may not reliably be able to report whether their hospital stay was prolonged or as expected. These two domains were, therefore, excluded from further consideration. The remaining 17 domains were formatted (operationalised) into items for the new outcome measure.

Items were written in plain language, informed by wording in existing tools with consideration of the issues raised in patient interviews surrounding any problematic words. Plain language descriptions were used, for example, to describe discharge and pus. In accordance with interviews findings, these words were considered to be medical terminology. They were, therefore, included in parentheses at the end of items in line with the novel design of the

outcome measure as a single tool for patient and healthcare professional completion, as described in the methods (Chapter 2). It was possible to include medical terminology in parentheses at the end of eight items/sub-items. Medical terminology was not included in other items simply because no relevant medical description existed for that sign, symptom or intervention and therefore a medical term was not considered necessary to include. For example, the item 'Has the wound been painful?' did not have a relevant medical description.

The first version of the measure prior to pre-testing (version 1.0) was structured to have 13 main items, with further information on signs/symptoms and wound care interventions captured using 11 additional questions (sub-items), is applicable (Table 3-7). This approach to use items and sub-items was taken with the aim to streamline the measure for quick completion, requiring the responder to only complete sub-items that were relevant. For example, if the response to the main item was "not at all" or "no", the responder could skip the associated sub-items and move on to the next main item (indicated by an arrow).

Resource use items

Of note, the preliminary version of the measure was designed to include additional sub-items purely to collect resource use data for the wider Bluebelle feasibility study. For example, information on the type of healthcare professional from whom advice was sought (for example, doctor or nurse), who dressed the wound and where (for example, doctor/nurse in the community or hospital, or family member/friend at home) and the type of antibiotic administered was collected, when applicable. These sub-items were not directly relevant to assess signs/symptoms and wound care interventions and, therefore, were not intended to be included in the final SSI measure.

Table 3-7. Items and response categories in the first version of the SSI measure prior to pre-testing (version 1.0)

	Item description	Response categories
1	Have you had any problems with the healing of your wound(s)?	Yes / No
2	Was the area around the wound warmer than the surrounding skin? (calor)	Not at all / A little / Moderately / Quite a bit / Very much
3	Was there redness spreading away from the edges of the wound? (erythema and cellulitis)	Not at all / A little / Moderately / Quite a bit / Very much
4	Was any part of the wound leaking fluid?	Not at all / A little / Moderately / Quite a bit / Very much
	a) Was it clear fluid? (serous exudate)	Not at all / A little / Moderately / Quite a bit / Very much
	b) Was it blood-stained? (haemoserous exudate)	Not at all / A little / Moderately / Quite a bit / Very much
	c) Was it thicker and yellow or green? (pus / purulent exudate)	Not at all / A little / Moderately / Quite a bit / Very much
	d) I do not know	Single tick box
5	Have the edges of any part of the wound separated?	Not at all / A little / Moderately / Quite a bit / Very much
	a) Did just the skin separate?	Not at all / A little / Moderately / Quite a bit / Very much
	b) Did the deeper tissue also separate?	Not at all / A little / Moderately / Quite a bit / Very much
6	Has the area around the wound become swollen?	Not at all / A little / Moderately / Quite a bit / Very much
7	Has the wound been smelly?	Not at all / A little / Moderately / Quite a bit / Very much
8	Has the wound been painful?	Not at all / A little / Moderately / Quite a bit / Very much
9	Have you had a raised temperature? (fever >38^{o}C)	Not at all / A little / Moderately / Quite a bit / Very much
10	Have you seen anyone because of your wound?	Yes / No /Don't know
11	Did anyone put a dressing on the wound?	Yes / No /Don't know
12	Have you been back into hospital for treatment of a problem with your wound?	Yes / No /Don't know
	a) Were you given antibiotics (as tablets or into a vein) for a wound infection, or wound abscess?	Yes / No /Don't know
	b) Was your wound reopened by a doctor or nurse?	Yes / No /Don't know

	Item description	Response categories
	c) Was your wound cleaned or drained? (debridement of wound/abscess/purulent drainage)	Yes / No /Don't know
	d) Did this include an operation under general anaesthetic? (debridement of wound, general anaesthetic)	Yes / No /Don't know
13	Have you had treatment for your wound elsewhere, for example at the GP surgery or at home?	Yes / No /Don't know
	a) Were you given antibiotics for your wound?	Yes / No /Don't know
	b) Was your wound reopened by a nurse or doctor, for example at the GP surgery or at home?	Yes / No /Don't know

3.4. Phase 3: Pre-testing the measure: content and face validity

3.4.1. Participants

Contact details of 41 interested patients (approached in hospital by surgical trainees and research nurses) were passed on to the author of this thesis. Of these 28/41 (68%) agreed to take part. Some 14 healthcare professionals that were contacted directly by the author of this thesis for participation and all (100%) agreed to take part. A total of 42 participants (28 patients; 14 healthcare professionals) were, therefore, recruited to take part in cognitive interviews to pre-test the measure (Figure 3-2). As described in the methods, modifications to the measure were subsequently tested with new participants (rather than being tested by the same participants) meaning each cognitive interview was undertaken with a different participant. Participant demographics are reported in Table 3-8.

Figure 3-2. Patients and healthcare professionals approached and recruited to pre-test the SSI measure

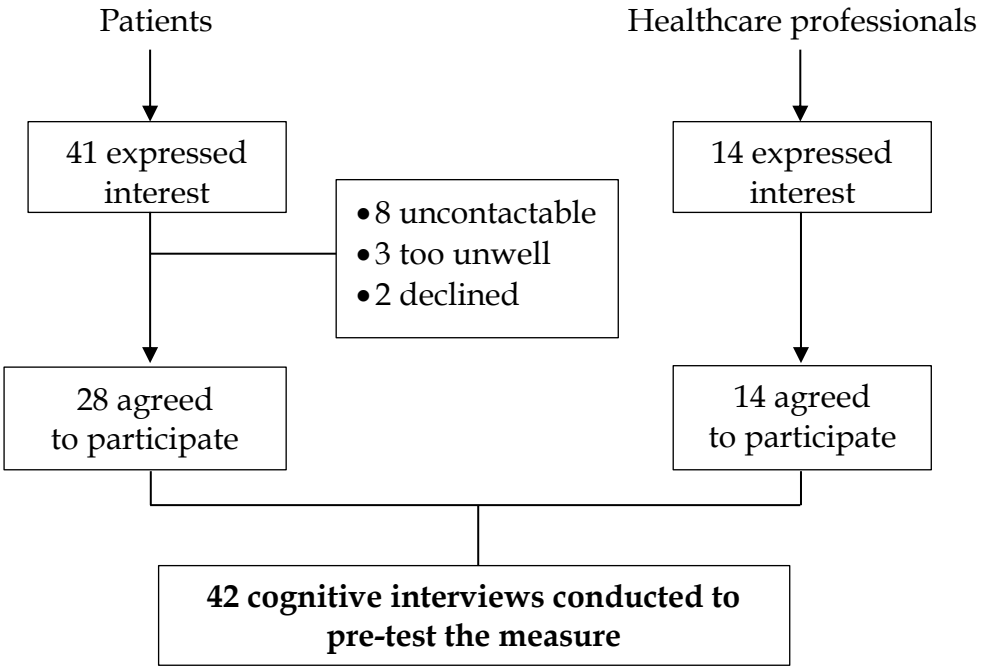


Table 3-8. Phase 3 participants: pre-testing the SSI outcome measure

		Healthcare professionals (n=14)	Patients (n=28)
Gender	Female	10	11
	Male	4	17
Age at time of interview (years)			
	21 to 30	0	1
	31 to 40	7	2
	41 to 50	3	2
	51 to 60	3	6
	>60	1	17
Role			
	Surgical trainee	4	-
	Hospital/Research nurse	3	-
	Midwife	3	-
	General practitioner	3	-
	Practice/Community nurse	1	-
Specialty			
	Upper/Lower GI surgery	6	-
	General practice/community	4	-
	Obstetrics	3	-
	Intensive care	1	-
Length of time qualified (years)			
	<10	1	-
	10-20	7	-
	>20	6	-
Time since surgery (weeks)			
	<1	-	1
	1-2	-	2
	2-4	-	9
	>4	-	16
Type of surgery			
	Lower GI	-	10
	Upper GI	-	9
	Hernia repair	-	6
	Caesarean	-	3

GI: gastrointestinal

3.4.2. Cognitive interview findings

One-to-one cognitive interviews were conducted with each participant, with a median duration of 27 minutes (range 13 to 52 minutes). The mean time between patients' surgery and pre-testing the measure was 46 days (range 6 to 208 days).

Throughout the cyclical process of interviews and analysis, interviews identified issues with item interpretation, understanding, and ambiguity. Many of these issues only became apparent because the combined use of plain language and medical terminology in items enabled the issues to be identified. For example, the inclusion of a medical term alongside plain language was found to directly affect the way an item was interpreted and, consequently, participants' responses in a way that enabled a problem with the plain language description to be identified. Specific examples of these findings are provided below. It was, therefore, an unexpected discovery during this phase of the work that the novel approach to combine plain language and medical terminology in items revealed to be a beneficial method to maximise content validity in outcome measure development. This methodological consideration to optimise questionnaire design has been published in detail [50].

Interview findings are summarised below under two themes: i) item interpretation and understanding and; ii) acceptability of the measure.

i) Item interpretation and understanding

Interviews highlighted where there was a need to modify items that were not interpreted or understood as intended. This occurred for several reasons, including a lack of precision and ambiguity in wording. Interviews also highlighted how the use of medical terminology improved understanding by focusing participants' response.

Example 1 – lack of precision

For example, the item intending to assess debridement of the wound (that is, the medical removal of dead, damaged, or infected tissue) was initially phrased "Has your wound been cleaned out? (debridement)". It became apparent that some participants who focused on the plain language description were interpreting the item differently to participants who also read and understood the medical terminology (Box 4). In this example, quotes are presented from two patient participants who responded "yes" to the item because the wound had been washed with saline solution or 'superficially' cleaned, demonstrating that the item was not being interpreted as precisely as intended.

Two quotes from healthcare professional participants further demonstrate that the plain language description was not an adequate reflection of the medical terminology. As a result of these observations, more detail was added to the plain language description to improve precision and ensure it more accurately reflected the wound care intervention intended to be assessed (debridement). The item was revised for testing in subsequent interviews and no further misinterpretations were found. This example demonstrates how it was the inclusion of medical terminology that specifically highlighted that the plain language description was ambiguous or insufficiently reflected the underlying issue intended to be assessed.

Box 4: Item interpretation and understanding: lack of precision of the underlying issue to be measured

Item: Has your wound been cleaned out? (debridement of wound)

Participant: " [reading] 'Has your wound been cleaned out?'...Yes it has been cleaned out...with this little plastic thing of liquid…saline stuff. They squirt this liquid in…put it on some gauze."

Patient participant, 1083

Participant: "I think... urm…when I had the staples taken out I think it was pretty standard practice for the nurse to just clean the wound before.… I don't know what she put on but it was a bit of cotton wool and she just rubbed…something."

Patient participant, 1104

Participant: "To me…cleaned out and debridement…isn't the same thing. Cleaned out is washing with saline and debridement is picking…slough…like yellow stuff out…or cutting dead skin away or scabs."

Healthcare professional participant, 3000

Participant: "When you say cleaning out of the wound do you just mean, like, getting some water?..."That [debridement] actually, to me, involves cutting…debridement is when you actually remove by cutting…or scraping…some dead tissue. Cleaned out, to me, just implies…oh, um, that you just gave it a bit of a clean…I completely understand what debridement of the wound means but, to me, cleaned out is not the same."

Healthcare professional participant, 1142

Revised item: Has your wound been cleaned out to remove any dead tissue? (debridement of wound)

Example 2 - ambiguity

Interviews further revealed ambiguity of some items that were written using plain language only, without a medical term. For example, some participants did not understand the meaning of the plain language description of the item 'Have the edges of any part of the wound separated?' (Box 5). The item was shown to be ambiguous and not specific enough to measure the intended underlying issue (wound dehiscence; cases where the wound had broken down). It was also found that that there was overlap with another item in the measure which intended to assess whether the wound edges had been intentionally separated by a doctor or nurse. As a result of these observations and with the aim to reduce ambiguity, a medical term ('spontaneous dehiscence') was added to the item and the plain language description was revised to 'Have the edges of any part of the wound separated on their own accord'. Subsequent interviews found that the inclusion of this medical term helped healthcare professionals to interpret this item correctly and ensured that only the more serious cases of wound breakdown were reported in the response to this item as intended.

Box 5: Item interpretation and understanding: ambiguity of the underlying issue to be measured

Item: Have the edges of any part of the wound separated?

Participant: "so what does that one mean?…so…it is separated…because it's not stitched up"…The actual wound was left open because they couldn't stitch it up."

Patient participant, 1079

Participant: "What does that [separated] mean – like cut or something? Got bigger?"

Patient participant, 1076

Revised item: Have the edges of any part of the wound separated on their own accord? (spontaneous dehiscence)

Example 3 – use of medical terminology to focus participants' response

One participant reported how their response to an item was directly influenced by the inclusion of the medical term, explaining that they would have interpreted the item differently, and subsequently responded differently, had the medical term not been included. The example is from a participant who experienced some bruising of the skin around the wound and explained how understanding the medical term focused their response (Box 6).

Box 6: Item interpretation and understanding: use of medical terminology to focus participants' response

Item: Was there redness spreading away from the edges of the wound? (erythema and cellulitis)

Participant: "In that first one [item], because I was describing the redness under the skin – more deeper redness, purple - when I read that first question, it was the fact that I had some idea of what erythema and cellulitis are…I thought, well it wasn't those…but ended up saying a little because of the redness… it probably was erythema…but I wasn't sure."

Interviewer: "And if we didn't have that erythema and cellulitis in there?…"

Participant: "Yeh, I would then have probably thought...that it was [asking about] that [bruising]... but because I recognised those [erythema and cellulitis]…I think I know more or less what those two things are."

Patient participant, 1081

ii) Acceptability

Participants' acceptability of the measure was overall positive. The format, length and response categories did not demonstrate problems, with only some minor modifications required. These are summarised below.

Views on the use of medical terminology alongside lay language in items were varied. Generally, patients reported that the inclusion of medical terms in parentheses was acceptable with the majority paying attention only to the lay wording. Some patients reported that they found the medical terms interesting and educational. Other patients reported that they only read the

plain language and ignored or did not notice the medical terms (Box 7). Patients did not report any concerns over the inclusion of medical terminology alongside plain language within the same item. In two interviews with healthcare professionals, however, concerns were expressed that the use of medical terminology in a questionnaire intended for patients may potentially generate worry or confusion. These healthcare professionals suggested that patients might be prompted to look up words on the internet and see distressing images. This was explored in subsequent interviews with patients. While two patients reported that they might look up the medical term on the internet out of curiosity, neither expressed any concerns that this may cause anxiety (Box 7).

Box 7: Acceptability of using plain language combined with medical terminology in a single measure

Participant: "I just skipped over it…I did say 'What's that?' but it didn't concern me because I could answer the question…I did make the comment of what [is that] but I didn't worry about it and I just went on to the next bit."

Patient participant, 1107

Participant: "I was...you know...interested [in the medical terms]. I didn't look at all of it…um, a couple I thought was interesting because it was Latin. That's what I thought. And also spontaneous dehiscence...I thought, gosh…so yeah I found it quite interesting."

Interviewer: "Did you find them[medical terms] confusing?"

Participant: "No…For instance that first one… I don't think I even saw…"

Patient participant, 1104

Participant: "If I was...on my own receiving this I am a bit of a google searcher so I would probably have looked them up."

Patient participant, 2030

3.4.3. Modifications to the preliminary version of the measure (version 1.0)

Summary of changes

In summary, pre-testing the preliminary measure (version 1.0) in a cyclical process of 42 interviews and analyses resulted in a total of eight versions (1.0 to 1.7) of the measure being tested.

Changes to wording and phrasing

The majority of changes during pre-testing concerned the wording and phrasing of items. Examples where plain language descriptions needed modifying have been described in the quotes in the previous paragraphs. Changes made to the wording and phrasing of items between the initial preliminary version (v1.0) and the final version after pretesting (v2.0) are presented in Table 3-9.

Changes to response categories

The response options for signs and symptom items were changed as a result of the pre-testing from five to four categories. The middle response option ('moderately') for items that assessed severity of signs/symptoms was dropped as participants reported that it was not a meaningful response option and had arbitrary interpretation. The response option 'very much' was changed to 'a lot' as it was found to make more grammatical sense when participants described the severity of signs and symptoms.

Changes to format and layout for effective completion of the measure

The format and layout of the measure was modified during pre-testing and subsequent revisions. Initially, items collecting information on wound care intervention were structured to first address whether participants had been back into hospital and/or seen in a primary care setting. Further sub-items then collected more detail on the wound care interventions that had occurred within each setting. Pre-testing found this to be a less streamlined layout for completing the measure than initially anticipated. The measure was therefore restructured so that participants were required to answer all items relevant to wound care interventions had occurred (regardless of the setting). This slightly increased the number of items that all participants were required to answer but reduced the number of sub-items, making it clearer for participants which items they were expected to complete than in earlier versions. The order of two items (assessing wound heat and wound redness) were reversed so the item assessing wound heat was not the first item in the measure. This modification was based on findings from cognitive interviews that wound heat may not always be straightforward for participants to answer (they may, for example, need to ask other people if they could not feel the wound area themselves due to numbness or if dressings are in place). Item order is important in questionnaire design and is known to influence response and participant engagement [115]. It was considered, therefore, important for the initial item in the measure to be an item that all participants could respond to easily in order to avoid potential disengagement from participants that may impact on participants' willingness to continue completing the measure, and ultimately risk reducing response rates.

Table 3-9. Changes to items in the preliminary version of the SSI measure as a result of pre-testing (Phase 3)

	Original item in preliminary version before pre-testing (version 1.0)	Item after pre-testing phase (version 2.0)	Summary and reason for change
1	Have you had any problems with the healing of your wound(s)?	n/a	Item removed - due to contradiction in reporting
2	Was the area around the wound warmer than the surrounding skin? (calor)	Was the area around the wound warmer than the surrounding skin?	Medical term dropped – found not to be commonly used in practice. No replacement term identified/required
3	Was there redness spreading away from the edges of the wound? (erythema and cellulitis)	Was there redness spreading away from the wound? (erythema/cellulitis)	Wording abbreviated – dropped "the edges of"
4	Was any part of the wound leaking fluid?	Was any part of the wound leaking fluid?	No change
	a) Was it clear fluid? (serous exudate)	Was it clear fluid? (serous exudate)	No change
	b) Was it blood-stained? (haemoserous exudate)	Was it blood-stained fluid? (haemoserous exudate)	No change
	c) Was it thicker and yellow or green? (pus / purulent exudate)	Was it thick and yellow/green? (pus / purulent exudate)	Minor grammatical / punctuation change
	d) I do not know	I do not know	No change
5	Have the edges of any part of the wound separated?	Have the edges of any part of the wound separated/gaped open on their own accord? (spontaneous dehiscence)	Wording expanded – added "/gaped open on their own accord" Medical term added
	a) Did just the skin separate?	Did the skin separate?	Wording abbreviated – dropped "just"
	b) Did the deeper tissue also separate?	Did the deeper tissue separate?	Wording abbreviated – dropped "also"
6	Has the area around the wound become swollen?	Has the area around the wound become swollen?	No change
7	Has the wound been smelly?	Has the wound been smelly?	No change
8	Has the wound been painful?	Has the wound been painful to touch?	Wording expanded – added "to touch"
9	Have you had a raised temperature? (fever >38^{o}C)	Have you had, or felt like you have had, a raised temperature or fever? (fever >38^{o}C)	Wording expanded – added "or felt like you have had"
10	Have you seen anyone because of your wound?	Have you sought advice because of a problem with your wound, other than at a planned follow-up appointment?	Major rephrase – found not to be specific enough

Original item in preliminary version before pre-testing (version 1.0)		Item after pre-testing phase (version 2.0)	Summary and reason for change
11	Did anyone put a dressing on the wound?	Has anything been put on the skin to cover the wound? (dressing)	Major rephrase – meaning found to be unclear Medical term added
12	Have you been back into hospital for treatment of a problem with your wound?	Have you been back into hospital for treatment of a problem with your wound?	No change
	a) Were you given antibiotics (as tablets or into a vein) for a wound infection, or wound abscess?	Have you been given antibiotics for a problem with your wound? If "Yes", Were the antibiotics given as tablets/liquid? Were the antibiotics given via a drip?	Restructured as one main item and two sub-items Rephrased - removed "or wound abscess"
	b) Was your wound reopened by a doctor or nurse?	Have the edges of your wound been deliberately separated by a doctor or nurse?	Restructured as a main item Major rephrase
	c) Was your wound cleaned or drained? (debridement of wound/abscess/purulent drainage)	Has your wound been scraped or cut to remove any unwanted tissue? (debridement of wound) Has your wound been drained? (drainage of pus /abscess)	Restructured as two main items Major rephrase
	d) Did this include an operation under general anaesthetic? (debridement of wound, general anaesthetic)	Have you had an operation under general anaesthetic for treatment of a problem with your wound?	Major rephrase One medical term dropped - meaning found to be unclear
13	Have you had treatment for your wound elsewhere, for example at the GP surgery or at home?	n/a	Item removed – accounted for in restructure
	a) Were you given antibiotics for your wound?	n/a	Item removed – accounted for in restructure
	b) Was your wound reopened by a nurse or doctor, for example at the GP surgery or at home?	n/a	Item dropped – accounted for in restructure

Final version of the measure after pre-testing (v2.0)

The version of the measure after pre-testing (version 2.0) included 16 items and five sub-items (Table 3-10). Of these, eight items (items 1 to 8) assessed SSI signs and symptoms and eight items (items 9 to 16) related to interventions for managing wounds and SSI. The five sub-items collected additional information on type of leaking fluid and wound dehiscence, when applicable. Medical terms were included in brackets in nine of the items/sub-items.

As previously described, additional sub-items (n=12) were included in the questionnaire to collect information on resource use purely for the purpose of the wider Bluebelle study. These were not directly relevant to SSI assessment and were not, therefore, treated as part of the outcome measure for evaluation.

Table 3-10. Items and response categories in the version of the SSI measure after pre-testing (version 2.0)

	Item	Response categories
1	Was there redness spreading away from the wound? (erythema/cellulitis)	Not at all / A little / Quite a bit / A lot
2	Was the area around the wound warmer than the surrounding skin?	Not at all / A little / Quite a bit / A lot
3	Was any part of the wound leaking fluid?	Not at all / A little / Quite a bit / A lot
	a) Was it clear fluid? (serous exudate)	Not at all / A little / Quite a bit / A lot
	b) Was it blood-stained fluid? (haemoserous exudate)	Not at all / A little / Quite a bit / A lot
	c) Was it thick and yellow/green fluid (pus/purulent exudate)	Not at all / A little / Quite a bit / A lot
	d) I do not know	Single tick box
4	Have the edges of any part of the wound separated/gaped open on their own accord? (spontaneous dehiscence)	Not at all / A little / Quite a bit / A lot
	a) Did the skin separate?	Not at all / A little / Quite a bit / A lot
	b) Did the deeper tissue separate?	Not at all / A little / Quite a bit / A lot
	c) I do not know	Single tick box
5	Has the area around the wound become swollen?	Not at all / A little / Quite a bit / A lot
6	Has the wound been smelly?	Not at all / A little / Quite a bit / A lot
7	Has the wound been painful to touch?	Not at all / A little / Quite a bit / A lot
8	Have you had, or felt like you have had, a raised temperature or fever? (fever >38^{o}C)	Not at all / A little / Quite a bit / A lot
9	Have you sought advice because of a problem with your wound, other than at a routine planned follow-up appointment?	Yes / No
10	Has anything been put on the skin to cover the wound? (dressing)	Yes / No
11	Have you been back into hospital for treatment with a problem with your wound?	Yes / No

	Item	Response categories
12	Have you been given antibiotics for a problem with you wound?	Yes / No / Don't know
13	Have the edges of your wound been deliberately separated by a doctor or nurse?	Yes / No / Don't know
14	Has your wound been scraped or cut to remove any unwanted tissue? (debridement of wound)	Yes / No / Don't know
15	Has your wound been drained? (drainage of pus/abscess)	Yes / No / Don't know
16	Have you had an operation under general anaesthetic for treatment of a problem with your wound?	Yes / No / Don't know

3.5. Phase 4 - Field-testing the measure: acceptability, reliability, construct and criterion validity

The methods chapter for this study described how field-testing was undertaken by administering the measure in two multicentre studies (a cohort study and a pilot RCT). Data from these two studies were combined in order to maximise data available for its evaluation.

3.5.1. Datasets

i) Cohort field-testing study

The cohort study ran between August 2015 and January 2016. Screening information was not formally collected as part of the cohort study protocol and therefore proportions of eligible and approached patients cannot reliably be reported. A total of 416 participants were recruited. Two participants were excluded shortly after recruitment (one died soon after surgery and one did not provide contact details). Data from the remaining 414 participants were available for analysis (Figure 3-3).

ii) Pilot RCT

The Bluebelle pilot RCT ran between March and November 2016. Of 1115 patients screened; 699 (73.4%) were eligible and approached; 415 (59.4%) of these consented to take part and 394 (56.4%) were randomised. Data from 378

participants were available for analysis (Figure 3-3). A consort diagram flow diagram of participants in the pilot RCT is provided in Appendix 17.

Available data from the cohort study and pilot RCT were combined, providing a total of 792 participants to contribute to the evaluation of the SSI measure (Figure 3-3). Participant demographics are presented in Table 3-11.

Figure 3-3. Participants and data contributing to the validation of the SSI measure.

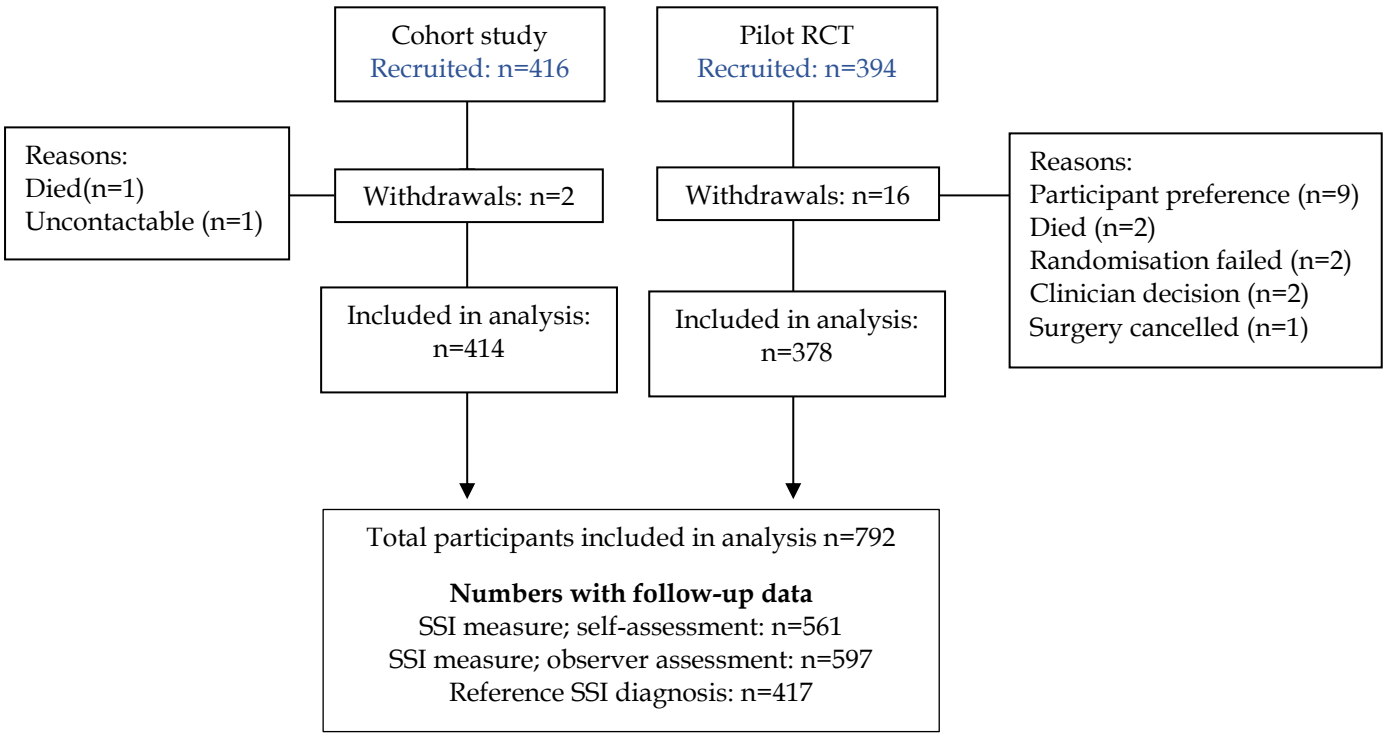


Table 3-11: Participant demographic, surgical and clinical details for field-testing the SSI measure (n=792)

Characteristic	n=792	Missing (n)
Age, years, mean (SD)	53.2 (17.5)	0
Male sex, n (%)	364 (46.0)	0
Ethnicity, n (%)		29
White	713 (93.4)	
Asian/Asian British	21 (2.8)	
Black/African/Caribbean/Black British	18 (2.4)	
Mixed/multiple ethnic groups	6 (0.8)	
Other	5 (0.7)	
Employment status*, n (%)		389
Full-time	138 (34.2)	
Part-time	40 (9.9)	
Self-employed	15 (3.7)	
Homemaker	12 (3.0)	
Retired	161 (40.0)	
Unable to work	18 (4.5)	
Unemployed	9 (2.2)	
Student	10 (2.5)	
Marital status*, n (%)		398
Married/civil partnership	247 (62.7)	
Divorced	19 (4.8)	
Cohabiting	36 (9.1)	
Separated	7 (1.8)	
Single	63 (16.0)	
Widowed	22 (5.9)	
Duration of surgery, n (%)		40
Less than 1 hour	213 (28.3)	
1 to 2 hours	182 (24.2)	
2 to 3 hours	139 (18.5)	
More than 3 hours	218 (29.0)	
Type of operation, n (%)		12
Cholecystectomy	102 (13.1)	
Caesarean section	95 (12.2)	
Colectomy/hemicolectomy	95 (12.2)	
Rectal/anterior resection	72 (9.2)	
Groin hernia repair	61 (7.8)	
Appendicectomy	57 (7.3)	
Pancreaticobiliary resection	38 (4.9)	
Small bowel resection	38 (4.9)	
Abdominal wall hernia repair	37 (4.7)	
Diagnostic laparoscopy / laparotomy	31 (4.0)	
Hartmann's procedure / reversal	21 (2.7)	
Stoma closure/reversal alone	19 (2.4)	
Oesophagogastric resection / gastrectomy	17 (2.2)	
Anti-reflux surgery	12 (1.5)	
Adhesiolysis	12 (1.5)	
Stoma formation alone	11 (1.4)	

	Bariatric surgery	6 (0.8)	
	Other	56 (7.2)	
Type of surgery, n (%)			47
	Elective	606 (81.3)	
	Unplanned	139 (18.7)	
Risk factor			
Smoking, n (%)			16
	current	114 (14.7)	
	Ex <1 month	236 (30.4)	
	No	426 (54.9)	
Diabetes, any type, n (%)		60 (7.7)	17
ASA score, n (%)			61
	I	232 (31.7)	
	II	373 (51.0)	
	III	118 (16.1)	
	IV	8 (1.1)	
BMI, mean (SD)		28.0 (6.1)	30

*Details collected for cohort participants only

3.5.2. Items for analysis

Version 2.0 of the new outcome measure was administered in the field-testing studies. All 16 items and five sub-items collecting further information on signs and symptoms were included for initial analysis. Participants' responses to these items and sub-items, showing the distribution of responses across the response options, are provided in Table 3-12. A graphical representation of the distribution of patients' responses is provided in Appendix 18. Sub-items that were included in the questionnaire purely for the purpose of collecting resource use data for the wider Bluebelle study (n=12) were not included in the analysis because they were not applicable to measuring SSI, as described previously.

Table 3-12. Distribution of responses for items from participant self-assessments (n=561) and HCP observer assessments (n=597)

Item		Distribution of responses							
		Not at all		A little		Quite a bit		A lot	
		n	%	n	%	n	%	n	%
1	Was there redness spreading away from the wound? (erythema/cellulitis)								
	Participant self-assessments	314	56.78	192	34.72	36	6.51	11	1.99
	HCP assessments	416	69.80	130	21.81	33	5.54	17	2.85
2	Was the area around the wound warmer than the surrounding skin?								
	Participant self-assessments	312	57.56	189	34.87	32	5.90	9	1.66
	HCP assessments	444	74.50	108	18.12	34	5.70	10	1.68
3	Was any part of the wound leaking fluid?								
	Participant self-assessments	351	63.93	125	22.77	45	8.20	28	5.10
	HCP assessments	419	71.02	116	19.66	26	4.41	29	4.92
3a)	Was it clear fluid? (serous exudate)								
	Participant self-assessments	48	40.34	51	42.86	17	14.29	3	2.52
	HCP assessments	80	51.61	58	37.42	10	6.45	7	4.52
3b)	Was it blood-stained fluid? (haemoserous exudate)								
	Participant self-assessments	45	28.48	77	48.73	24	15.19	12	7.59
	HCP assessments	77	46.67	56	33.94	18	10.91	14	8.48
3c)	Was it thick and yellow/green fluid? (pus/purulent exudate)								
	Participant self-assessments	71	57.26	27	21.77	18	14.52	8	6.45
	HCP assessments	96	61.94	30	19.35	13	8.39	16	10.32
4	Have the edges of any part of the wound separated/gaped open on their own accord? (spontaneous dehiscence)								
	Participant self-assessments	423	78.04	93	17.16	17	3.14	9	1.66
	HCP assessments	489	83.59	76	12.99	11	1.88	9	1.54
4a)	Did the skin separate?								
	Participant self-assessments	41	28.52	78	52.35	20	13.42	10	6.71
	HCP assessments	17	15.60	71	65.14	11	10.09	10	9.17

4b)	Did the deeper tissue separate?								
	Participant self-assessments	93	75.61	15	12.20	11	8.94	4	3.25
	HCP assessments	77	79.38	10	10.31	4	4.12	6	6.19
5	Has the area around the wound become swollen?								
	Participant self-assessments	345	63.07	160	29.25	35	6.40	7	1.28
	HCP assessments	481	80.70	96	16.11	12	2.01	7	1.17
6	Has the wound been smelly?								
	Participant self-assessments	488	90.54	36	6.68	9	1.67	6	1.11
	HCP assessments	547	91.78	31	5.20	13	2.18	5	0.84
7	Has the wound been painful to touch?								
	Participant self-assessments	207	37.77	274	50.00	50	9.12	17	3.10
	HCP assessments	351	58.79	180	30.15	51	8.54	15	2.51
8	Have you had, or felt like you have had, a raised temperature or fever? (fever >38^{o}C)								
	Participant self-assessments	462	85.40	57	10.54	11	2.03	11	2.03
	HCP assessments	524	87.92	37	6.21	15	2.52	20	3.36

		No		**Yes**	
		n	**%**	**n**	**%**
9	Have you sought advice because of a problem with your wound, other than at a routine planned follow-up appointment?				
	Participant self-assessments	396	71.10	161	28.90
	HCP assessments	442	75.04	147	24.96
10	Has anything been put on the skin to cover the wound? (dressing)				
	Participant self-assessments	333	60.00	222	40.00
	HCP assessments	396	66.78	197	33.22
11	Have you been back into hospital for treatment with a problem with your wound?				
	Participant self-assessments	514	94.49	30	5.51

	HCP assessments	548	95.30	27	4.70		

		No		Yes		Don't know	
		n	%	n	%	n	%
12	Have you been given antibiotics for a problem with you wound?						
	Participant self-assessments	463	83.88	82	14.86	7	1.27
	HCP assessments	511	86.32	81	13.68	0	0
13	Have the edges of your wound been deliberately separated by a doctor or nurse?						
	Participant self-assessments	532	96.03	16	2.89	6	1.08
	HCP assessments	572	96.46	21	3.54	0	0
14	Has your wound been scraped or cut to remove any unwanted tissue? (debridement of wound)						
	Participant self-assessments	539	98.36	6	1.09	3	0.55
	HCP assessments	588	98.99	6	1.01	0	0
15	Has your wound been drained? (drainage of pus/abscess)						
	Participant self-assessments	518	95.40	21	3.87	4	0.74
	HCP assessments	580	97.97	11	1.86	1	0
16	Have you had an operation under general anaesthetic for treatment of a problem with your wound?						
	Participant self-assessments	542	99.27	2	0.37	2	0.37
	HCP assessments	590	100.00	0	0	0	0

Percentages shown for the distribution of response across the response categories do not include missing data

3.5.3. Acceptability

Response rates

i) Patient-completed assessments (self-assessments)

A total of 561/792 (70.8%) participants completed and returned self-assessments (Figure 3-4). Attempts to collect reasons for non-completed self-assessment were not part of the study designs, therefore reasons for non-response are unknown. Demographics and operative details of the responders are reported in Table 3-13. Participants had a mean age of 56.3 (SD 16.5), approximately half were male (n=278; 49.6%) and most had undergone elective surgery (n=453; 80.8%). Self-assessments were completed a median of 29 days (inter-quartile range 24 to 33 days) after surgery.

ii) Healthcare professional (observer)-completed assessments

Observer assessments were completed for 597/791 (75.5%) participants (Figure 3-4). The reason for non-completed observer assessments was primarily due to not being able to contact the participant by telephone or meet them face-to-face. Observer assessments were undertaken a median of 37 days (inter-quartile range 32 to 48 days) after surgery.

iii) Non-responders (participants for whom a self- and/or observer-completed assessment was not available)

A self-assessment and/or an observer assessment was available for 688/792 (86.9%) participants. The remaining 104/792 (13.1%), therefore, were complete non-responders (i.e. did not return the self-assessment and it was

not possible to conduct an observer assessment via telephone or face-to-face) (Figure 3-4). Demographics and operative details of these participants were similar to those who completed a self-assessment (Table 3-13). A higher proportion of non-responders, however, had unplanned surgery compared with those who completed and returned a self-assessment (n= 34; 34.3% versus n=76; 14.4% versus respectively, p<0.001).

Figure 3-4. Participant self- and observer assessments available for analysis

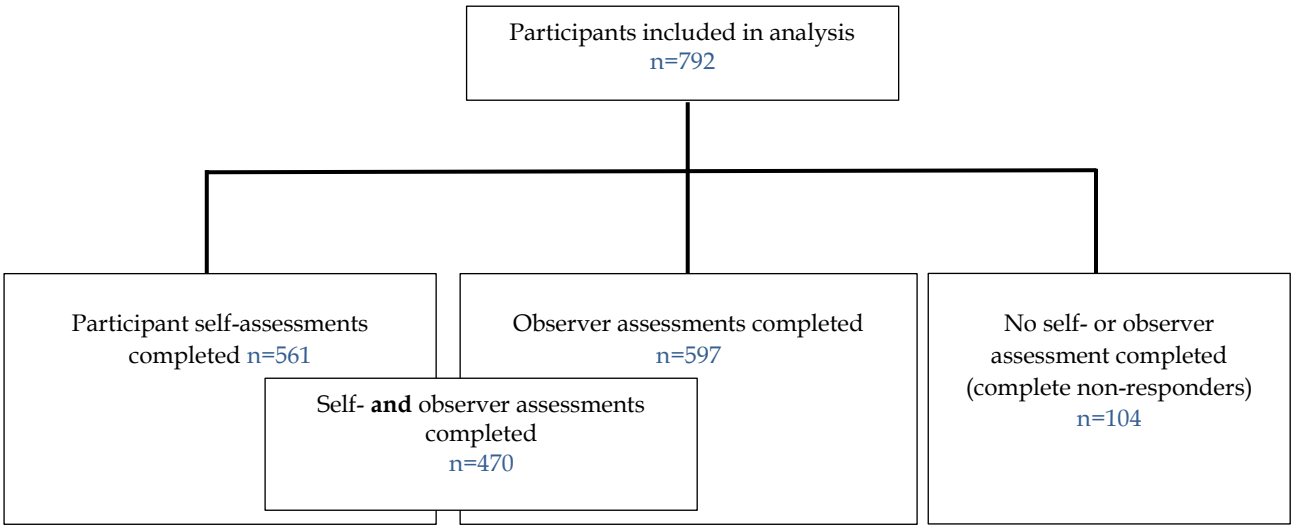


Table 3-13. Demographics and operative details for participants who completed the self-assessment (n=561), compared with participants for whom no self- or observer assessment was obtained (complete non-responders; n=104).

	Completed self-assessments (n=561)	**No self- or observer assessment (complete non-responder) (n=104)**
Male (%)	278 (49.6)	43 (41.4)
Mean age (SD)	56.3 (16.5)	47.0 (18.4)
ASA grade (%)		
I	146 (28.6)	37 (38.1)
II	277 (54.3)	39 (40.2)
III	81 (15.9)	20 (20.6)
IV	6 (1.2)	1 (1.0)
missing	51	7
Surgery (%)		
Elective	453 (85.6)	65 (65.7)
Unplanned	76 (14.4)	34 (34.3)
missing	32	5

Answers to debriefing questions

The debriefing questionnaire was posted to participants in the cohort study only. Data were available from 302/414 (72.9%) responders.

The majority of responders 276/302 (91.4%) reported that it took less than 10 minutes to complete a self-assessment. Very few participants required help to complete any of the items or found any of the items difficult or confusing to answer (Table 3-14).

Table 3-14: Feasibility and practicality of completing the SSI measure (participant self-assessment; n=302)

Debriefing item	n	(%)
Time taken to complete the outcome measure (%)		
<5 mins	167	(55.3)
6-10 mins	109	(36.1)
>10 mins	26	(8.6)
Help needed to answer ≥1 item (%)	15	(5.0)
Confusion / difficulty answering ≥1 item (%)	18	(6.0)

Available free text responses providing reasons for needing help to answer items, or why items were difficult or confusing, were summarised into categories (Table 3-15). Reasons included practical issues such as not being able to see or touch the wound easily due to its location. Other reasons were due to uncertainty on whether the item was applicable for a minority of participants. One participant need help to with translating the items despite lack of ability to read/understand English being an exclusion criterion for recruitment into the study.

Table 3-15. Reported reasons for needing help to complete items in the SSI measure

Reported reason for needing help	Total number reporting problem/ reason	Example free-text quotes from debriefing questionnaire
Uncertainty whether item or response option was applicable	*6*	*"Didn't have any pain but did if you pressed it"* *"Stitch was pulled out and left tiny wet hole – I did not know if this applied"* *"Pain and discomfort may be low when relaxed but significant when active or have a cold"* *"I found it confusing as temperatures might have nothing to do with the wound"* *"I was looking for an option that said 'blood'. I selected 'blood stained fluid' as this was the closest option"* *"My response didn't fit any category i.e. I 'did know' but the 3 options didn't fit my answer 'orange fluid'."*
Location of wound	*5*	*"All pains under bottom, rely on help"* *"Stoma bag [problem with seeing wound]"* *"Asked wife about was it warmer"*
Lack of knowledge	*2*	*"What constitutes a dressing"* *"Not sure how to describe plaster/dressing. Perhaps a number of options could be offered."*
Recall	*2*	*"… would have been useful to have the questionnaire while my wound was at the early stages- not 1 month in."* *"… many wounds will have healed before 1 month so it's difficult to remember early stages."*
No context / prior experience of wounds	*2*	*"Difficult to answer some of the questions without any context. I've never had another wound, so I don't know what 'a little' fluid is."* *"Without any previous experience of wounds it's difficult to know the difference between answers- a little/quite a bit"*
Language	*1*	*"Needed translation"*

Missing data

As described previously, sub-items were not expected to be completed if the response to the main item was "not at all" or "no". For all other responses, the sub-items were expected to be completed. Missing data are described separately for i) items and ii) sub-items due to a substantial observed difference in the degree of missing responses.

i) Items 1 to 16

Missing data for items 1 to 16 were few, ranging from 0.7% to 3.9% in participant self-assessments and 0.0% to 3.7% in observer assessments. (Table 3-16). Participant self-assessments had fewer than 2.7% of responses missing for 10 of the 16 items, and fewer than 3.9% of responses missing for any of the 16 items overall. Observer assessments had fewer than 2.0% of responses missing for all items with the exception of Item 11 (missing 3.7% of responses). One explanation for the higher level of missing data for this item compared to other items could because Item 11 was the last item on the second page before continuing over on the final page. It may, therefore, have been missed in error.

ii) Sub-items 3a, 3b, 3c and 4a, 4b

A total of five sub-items were included in the outcome measure to collect more information on the type of leaking fluid (sub-items 3a, 3b and 3c) and the extent of wound dehiscence (sub-items 4a and 4b). These sub-items were intended to be completed if the response to the main item was anything other than 'not at all' (i.e. reports of 'a little', 'quite a bit' or 'a lot' of the sign/symptom).

Missing responses to the sub-items ranged between 5.0% and 43.4% of participant self-assessments (Table 3-16). Missing responses to these sub-items in observer assessments were fewer (ranging between 6.3% and 16.7%) although the levels were still concerning. Levels of missing data over 15% were considered not acceptable [46], as defined in the methods (Chapter 2). A closer examination of these data showed that, in some cases, there was inconsistency in completed responses. Some respondents did not complete any of the sub-items when a response would have been expected. Other respondents completed only one of the sub-items rather than all of them, as intended. For example, responses to sub-item 3a "Was it clear fluid?" were completed, whereas the remaining sub-items 3b "Was it blood-stained fluid?" and 3c "Was it thick and yellow/green fluid?" were left missing when they were intended to be completed. If the participant had not experienced the type of leaking fluid the response was intended to be marked as 'not at all'. Instead, data indicated that respondents were skipping sub-items that were not relevant to them. The high level of missing responses to the sub-items indicted the current design was suboptimal and highlighted a need to reconsider the format and layout of the questionnaire to minimise missing data.

Table 3-16. Levels of missing data for items in participant self-assessments (n=561) and observer assessments (n=597)

		Missing data			
		Self-assessments		Observer assessments	
	Item*	n	%**	n	%**
9	Have you sought advice because of a problem with your wound, other than at a routine planned follow-up appointment?	4	0.71	8	1.34
10	Has anything been put on the skin to cover the wound? (dressing)	6	1.07	4	0.67
13	Have the edges of your wound been deliberately separated by a doctor or nurse?	7	1.25	4	0.67
1	Was there redness spreading away from the wound? (erythema/cellulitis)	8	1.43	1	0.17
12	Have you been given antibiotics for a problem with you wound?	9	1.60	5	0.84
3	Was any part of the wound leaking fluid?	12	2.14	7	1.17
7	Has the wound been painful to touch?	13	2.32	0	0
14	Has your wound been scraped or cut to remove any unwanted tissue? (debridement of wound)	13	2.32	3	0.50
5	Has the area around the wound become swollen?	14	2.50	1	1.17
16	Have you had an operation under general anaesthetic for treatment of a problem with your wound?	15	2.67	7	1.17
11	Have you been back into hospital for treatment with a problem with your wound?	17	3.03	22	3.69
15	Has your wound been drained? (drainage of pus/abscess)	18	3.21	5	0.84
2	Was the area around the wound warmer than the surrounding skin?	19	3.39	1	0.17
4	Have the edges of any part of the wound separated/gaped open on their own accord? (spontaneous dehiscence)	19	3.39	12	2.01
8	Have you had, or felt like you have had, a raised temperature or fever? (fever >38°C)	20	3.57	1	0.17
6	Has the wound been smelly?	22	3.92	1	0.17
4a)	Did the skin separate?	6	5.04	6	6.25
4b)	Did the deeper tissue separate?	27	22.69	16	16.67
3b)	Was it blood-stained fluid? (haemoserous exudate)	47	23.74	14	8.19
3c)	Was it thick and yellow/green fluid? (pus/purulent exudate)	81	40.61	23	13.45
3a)	Was it clear fluid? (serous exudate)	86	43.43	23	13.45

*Items are ordered in ascending (fewest to most) order of missing data in participant self-assessments

**shows proportion of participants missing a response to that item in otherwise completed questionnaires. For sub-items, shows the proportion of participants missing a response if a response was expected (based on the response to the main item).

3.5.4. Reliability

Test-retest reliability

A total of 44/50 (88.0%) participants completed the self-assessment on two separate occasions to examine test-retest reliability of the measure. The median time between test-retest assessments was five days (inter-quartile range: four to seven days). This was within the one-week interval period intended. There was no change in any of the participants' health between the test-retest time period, based on responses to the 'anchor' question (Item 11; "Have you been back into hospital for treatment of a problem with your wound?").

Test-retest reliability was good for the majority of items, with Kappa statistic values within the range (0.4 to 0.75) considered to be fair to good agreement [46]. Observed agreement in responses between the test-retest assessments was high, with over 86% agreement for all 16 items. For some items, calculation of a kappa statistic was not reliable because there were too few observations in any one cell of the cross-tabulation. When numbers in contingency tables were sufficient and it was possible to produce kappa statistics, values were greater than 0.6 for the majority of items (Table 3-17). Stability of responses for items with a 4-category response option between test-retest assessments are shown in Figure 3-5. The proportion of participants with identical responses (values of 0) or moving only one category (values of -1 or 1) ranged between 95% to 100%.

Table 3-17. Patient assessment test-retest reliability for each item (sub-sample of cohort study; n=44)

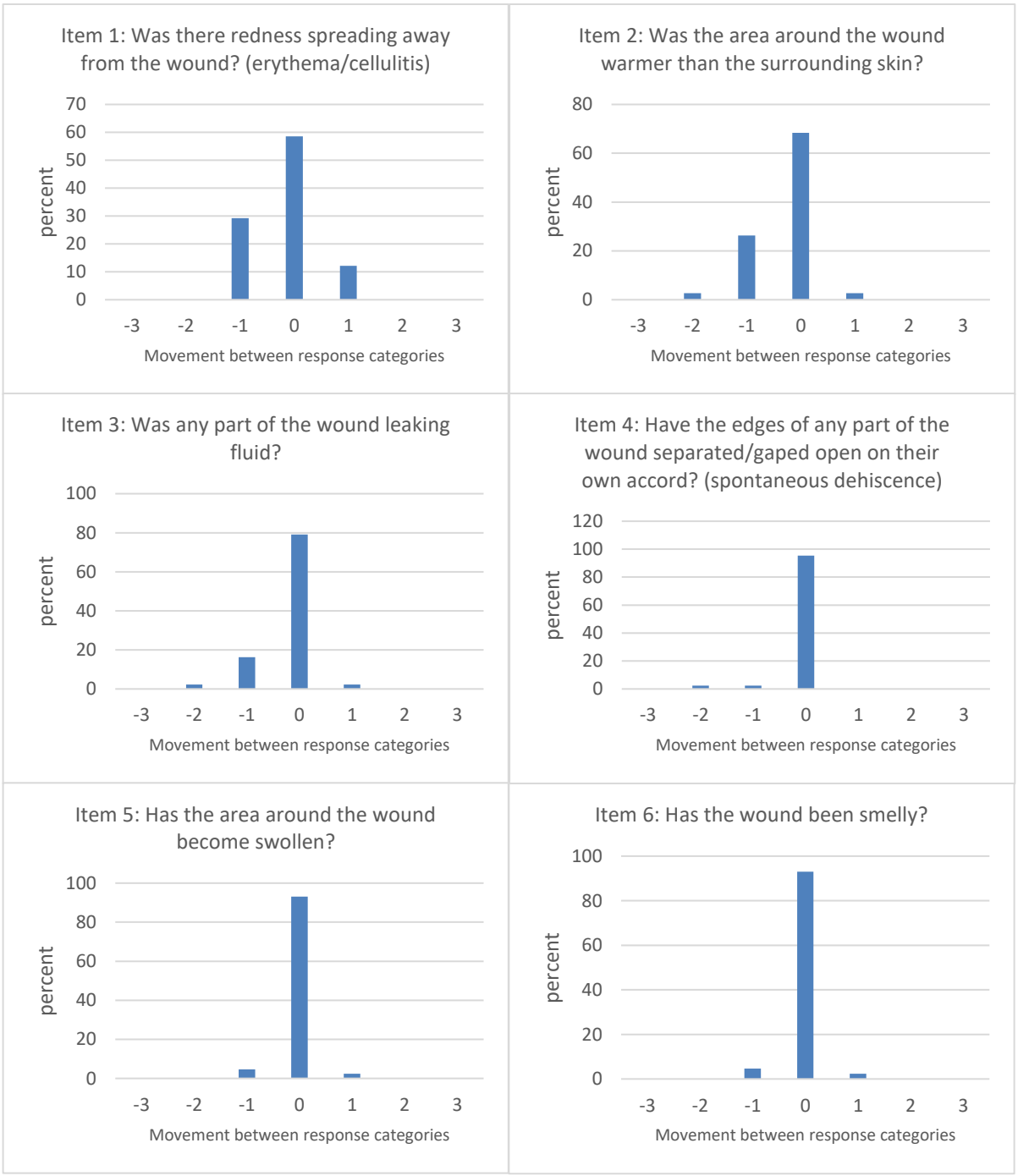
Item*		N	Observed agreement (%)	Expected agreement (%)	Weighted Kappa
3a	Was it clear fluid? (serous exudate)	4	100.00	87.50	1.0000
4a	Did the skin separate?	8	100.00	87.50	1.0000
4b	Did the deeper tissue separate?	6	100.00	87.50	1.0000
11	Have you been back into hospital for treatment with a problem with your wound?	44	100.00	83.47	1.0000
15	Has your wound been drained? (drainage of pus/abscess)	41	100.00	95.24	1.0000
10	Has anything been put on the skin to cover the wound? (dressing)	44	97.73	50.62	0.9540
4	Have the edges of any part of the wound separated/gaped open on their own accord? (spontaneous dehiscence)	43	97.67	84.41	0.8509
12	Have you been given antibiotics for a problem with you wound?	43	95.35	75.88	0.8072
3b	Was it blood-stained fluid? (haemoserous exudate)	11	93.94	74.10	0.7660
3c	Was it thick and yellow/green fluid (pus/purulent exudate)	5	86.67	54.67	0.7059
3	Was any part of the wound leaking fluid?	43	92.25	73.79	0.7043
9	Have you sought advice because of a problem with your wound, other than at a routine planned follow-up appointment?	43	86.05	55.98	0.6830
5	Has the area around the wound become swollen?	44	93.18	81.82	0.6250
7	Has the wound been painful to touch?	43	91.47	79.43	0.5854

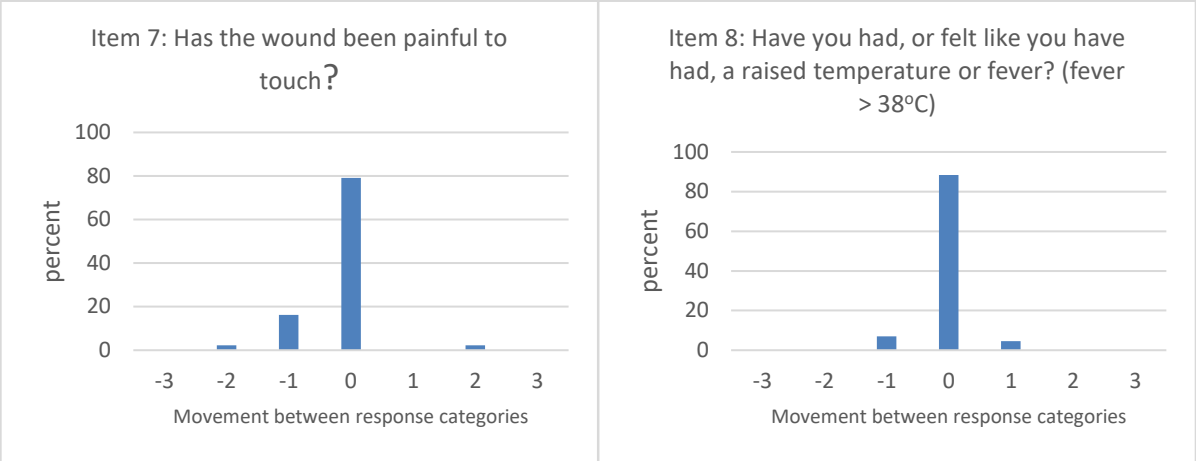
Item*		N	Observed agreement (%)	Expected agreement (%)	Weighted Kappa
8	Have you had, or felt like you have had, a raised temperature or fever? (fever >38^{o}C)	43	96.12	93.74	0.3804
6	Has the wound been smelly?	43	97.67	96.34	0.3645
2	Was the area around the wound warmer than the surrounding skin?	38	88.60	82.46	0.3500
1	Was there redness spreading away from the wound? (erythema/cellulitis)	41	86.18	80.11	0.3051
13	Have the edges of your wound been deliberately separated by a doctor or nurse?	43	97.67	97.67	0.0000
14	Has your wound been scraped or cut to remove any unwanted tissue? (debridement of wound)	39	94.87	95.00	-0.0263
16 †	Have you had an operation under general anaesthetic for treatment of a problem with your wound?	40	100.00	-	-

*Items ordered in descending (highest to lowest) values of Kappa statistic. Values between 0.4 and 0.75 were considered to be fair to good agreement [46]

†Expected agreement and Kappa statistic not possible to compute as all observations were of the same category ('No')

Figure 3-5. Stability of responses between test-retest assessments for items assessing signs and symptoms





Comparison of responses between participant self- and observer assessments

Data from both a participant self-assessment and an observer assessment were available for 470/791 (59.4%) participants (Figure 3-4). Median time between self- and observer assessments was eight days (inter-quartile range two to 16 days). Overall, responses in the self- and observer assessments were similar, demonstrated in graphical format in Figure 3-6 (individual data) and Figure 3-7 (group data). Numerical data are available in Table 3-12. Agreement in cross-tabulations of self- and observer responses for each participant was generally high. Levels of observed agreement was greater than 84.3% for all items. Where it was possible to calculate a Kappa statistic, values were between 0.40 and 0.74 (indicating fair to good agreement) with the exception of one item (Table 3-18).

Figure 3-6. Comparison of responses to items in self- and observer assessments, individual data

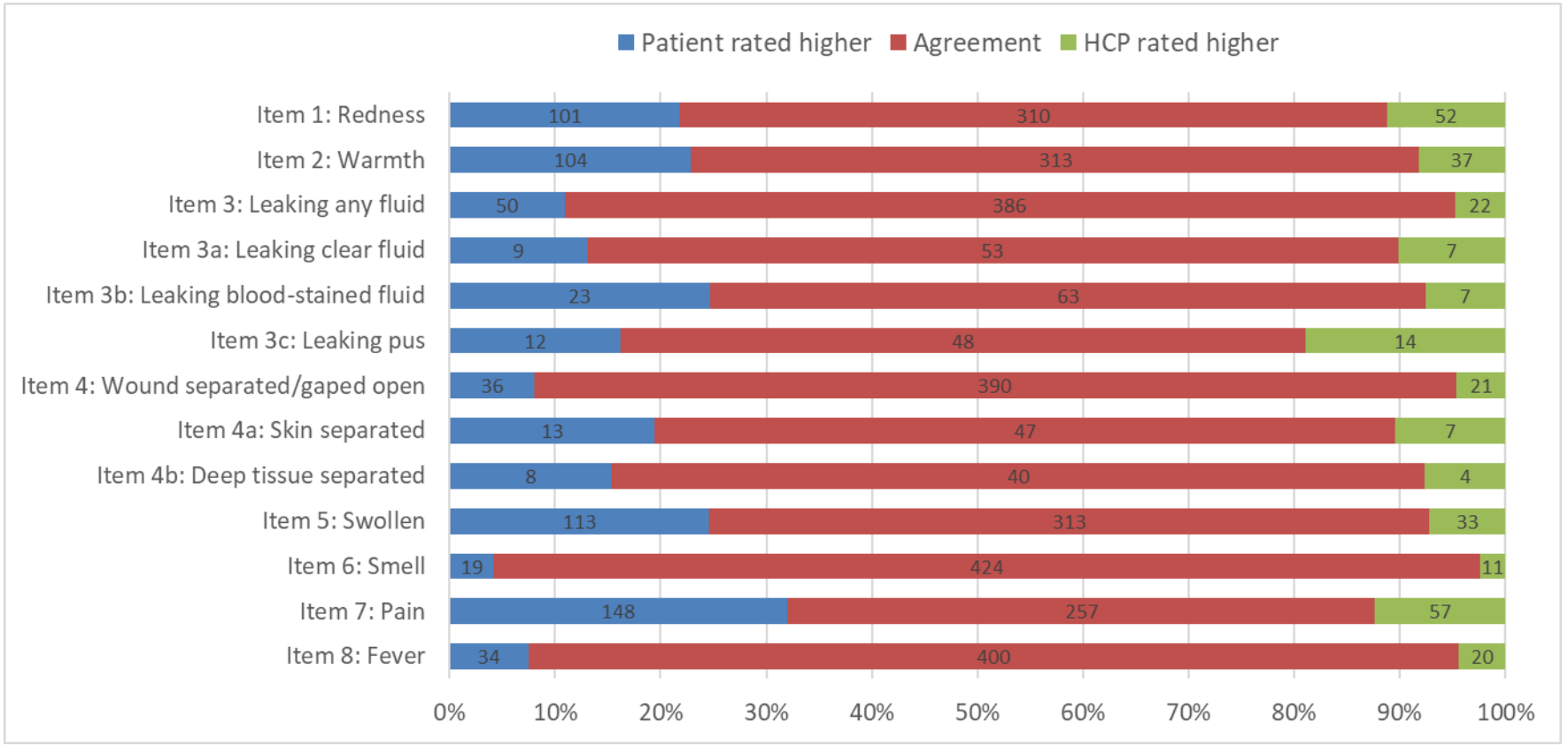
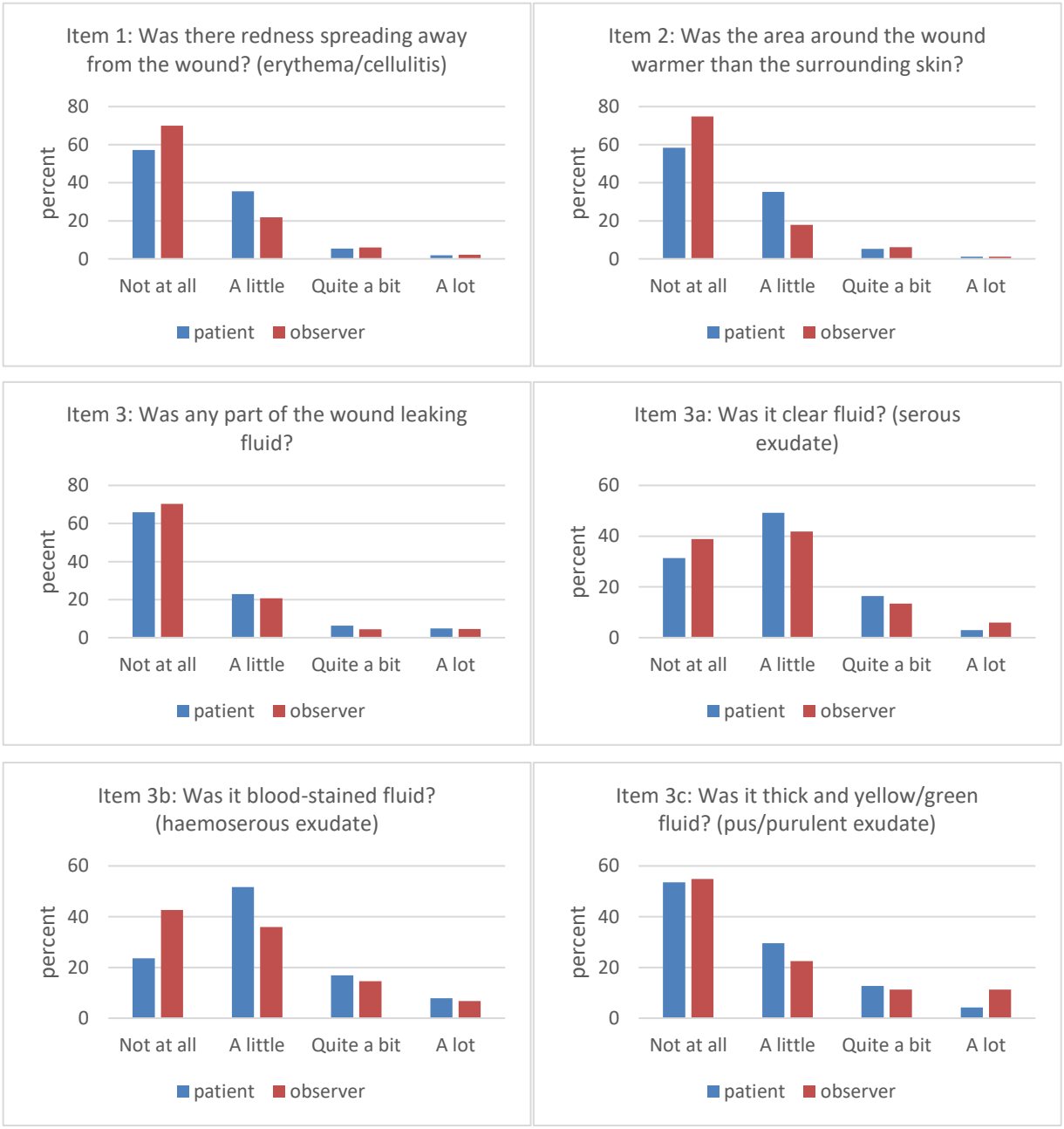
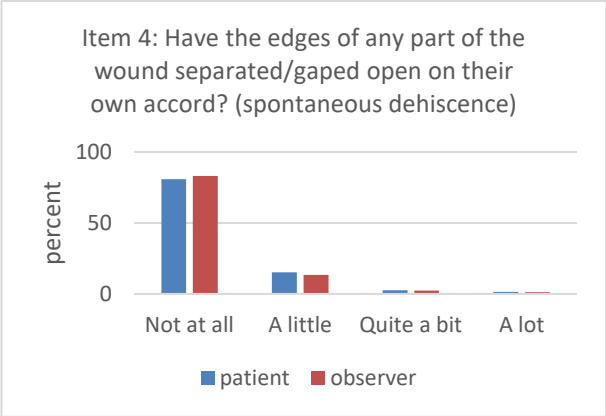
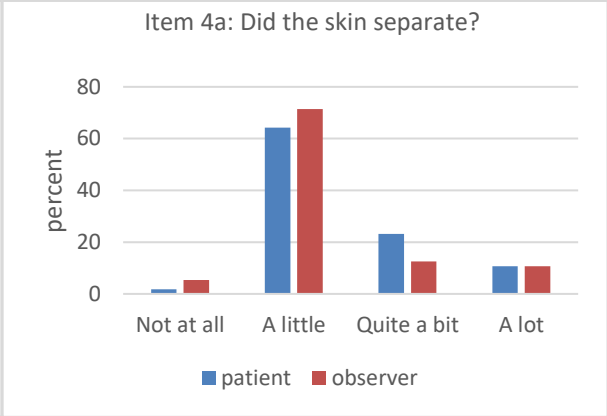
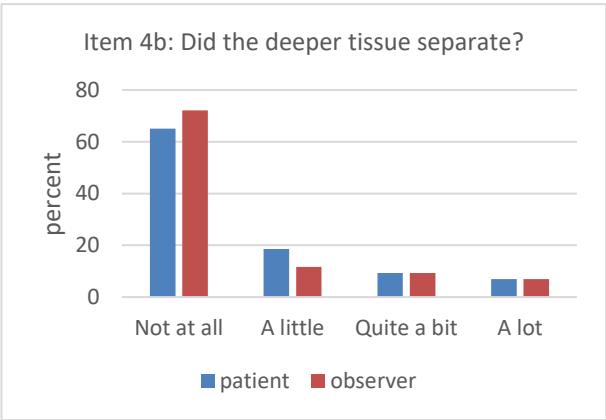


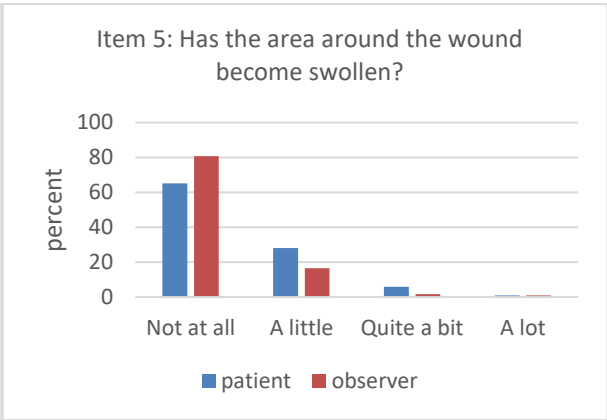
Figure 3-7. Comparison of responses to items in self- and observer assessments, for participants with data from both assessments (n=470).

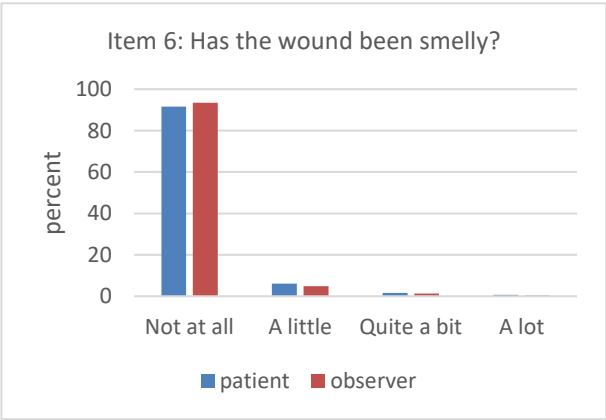


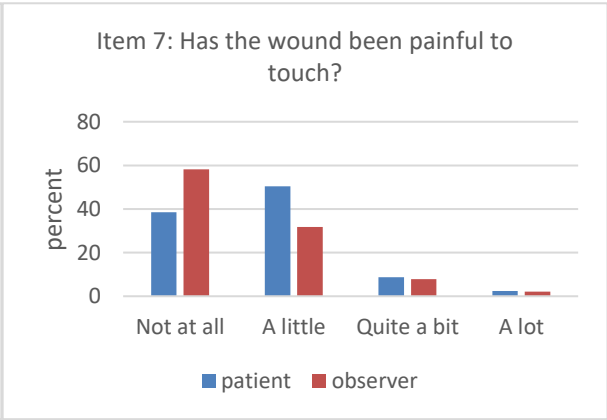

Item 4: Have the edges of any part of the wound separated/gaped open on their own accord? (spontaneous dehiscence)
percent
100
50
0
Not at all
A little
Quite a bit
A lot
patient
observer

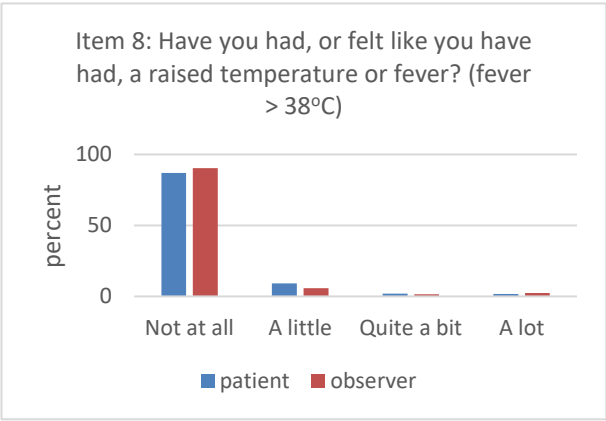

Item 4a: Did the skin separate?
percent
80
60
40
20
0
Not at all
A little
Quite a bit
A lot
patient
observer

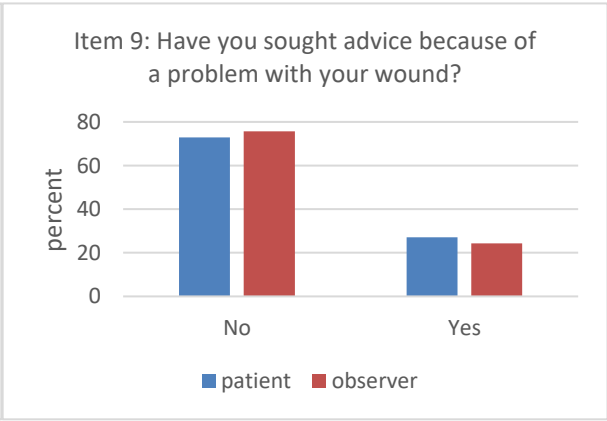

Item 4b: Did the deeper tissue separate?
percent
80
60
40
20
0
Not at all
A little
Quite a bit
A lot
patient
observer

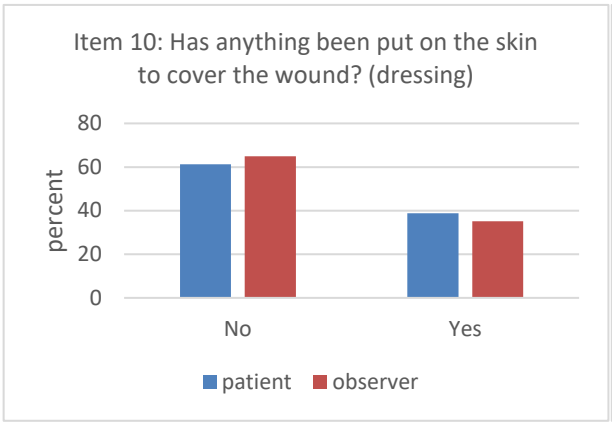

Item 5: Has the area around the wound become swollen?
percent
100
80
60
40
20
0
Not at all
A little
Quite a bit
A lot
patient
observer

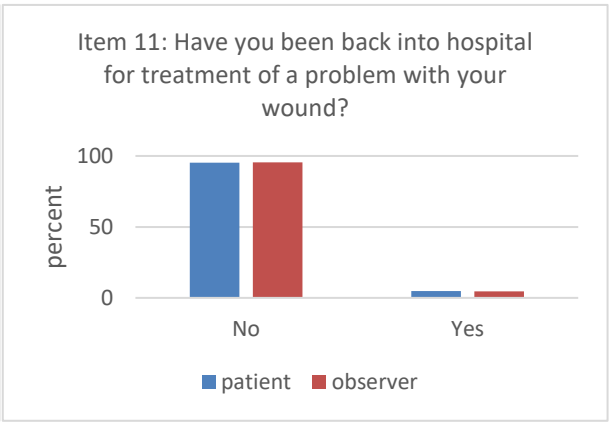

Item 6: Has the wound been smelly?
percent
100
80
60
40
20
0
Not at all
A little
Quite a bit
A lot
patient
observer

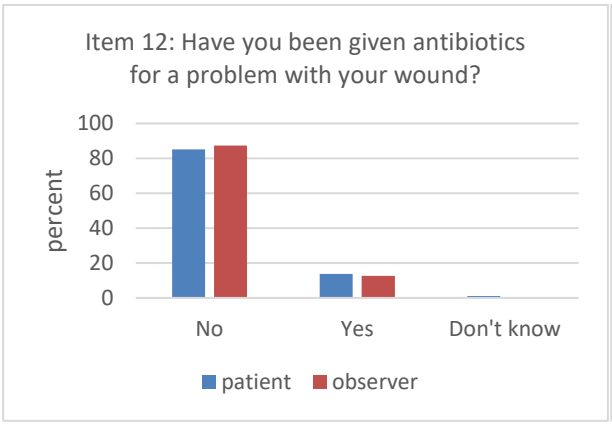

Item 7: Has the wound been painful to touch?
percent
80
60
40
20
0
Not at all
A little
Quite a bit
A lot
patient
observer

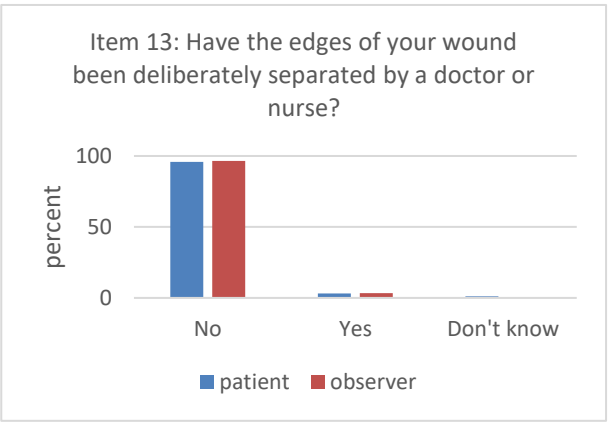

Item 8: Have you had, or felt like you have had, a raised temperature or fever? (fever > 38°C)
percent
100
50
0
Not at all
A little
Quite a bit
A lot
patient
observer

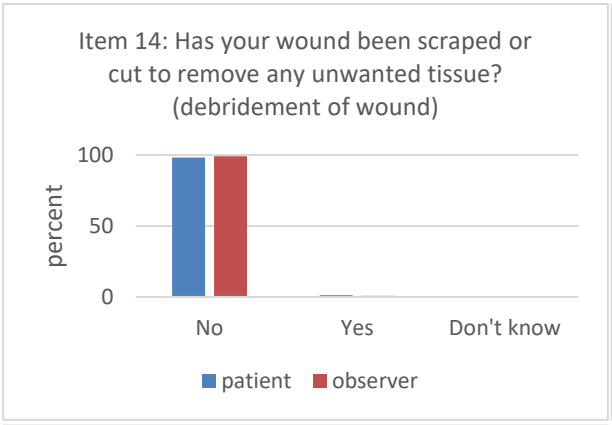

Item 9: Have you sought advice because of a problem with your wound?
percent
80
60
40
20
0
No
Yes
patient
observer

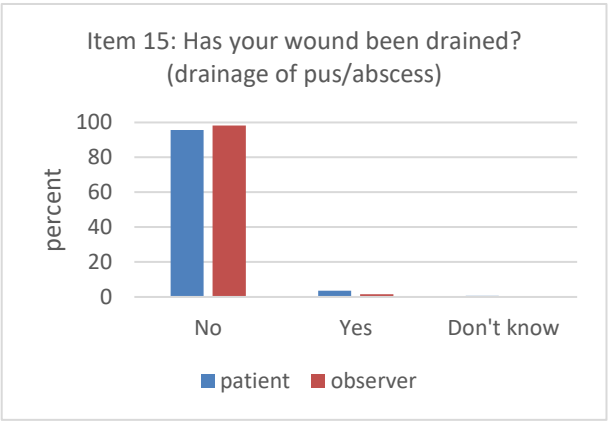

Item 10: Has anything been put on the skin to cover the wound? (dressing)
percent
80
60
40
20
0
No
Yes
patient
observer


Item 11: Have you been back into hospital for treatment of a problem with your wound?
percent
100
50
0
No
Yes
patient
observer


Item 12: Have you been given antibiotics for a problem with your wound?
percent
100
80
60
40
20
0
No
Yes
Don't know
patient
observer


Item 13: Have the edges of your wound been deliberately separated by a doctor or nurse?
percent
100
50
0
No
Yes
Don't know
patient
observer


Item 14: Has your wound been scraped or cut to remove any unwanted tissue? (debridement of wound)
percent
100
50
0
No
Yes
Don't know
patient
observer


Item 15: Has your wound been drained? (drainage of pus/abscess)
percent
100
80
60
40
20
0
No
Yes
Don't know
patient
observer

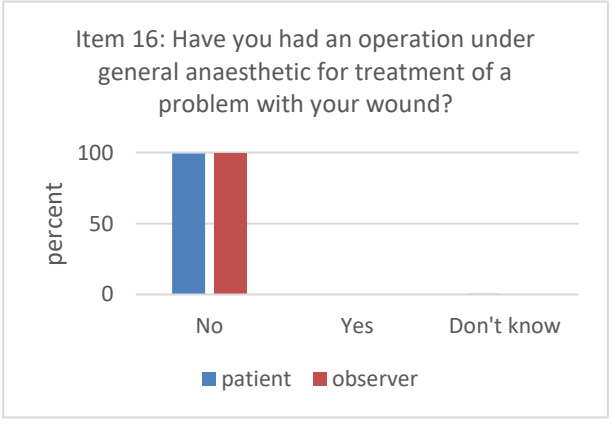

Item 16: Have you had an operation under general anaesthetic for treatment of a problem with your wound?
percent
100
50
0
No
Yes
Don't know
patient
observer

Table 3-18: Agreement between responses in participant and HCP assessments, for participants with data from both assessments (n=470)

Item*		N	Observed agreement (%)	Expected agreement (%)	Weighted Kappa
12	Have you been given antibiotics for a problem with you wound?	454	96.26	76.89	0.8379
3	Was any part of the wound leaking fluid?	458	93.96	76.48	0.7432
10	Has anything been put on the skin to cover the wound? (dressing)	464	84.70	53.33	0.6721
3a	Was it clear fluid? (serous exudate)	67	90.55	71.43	0.6691
4b)	Did the deeper tissue separate?	43	91.03	74.68	0.6456
4	Have the edges of any part of the wound separated/gaped open on their own accord? (spontaneous dehiscence)	447	95.15	86.85	0.6314
9	Have you sought advice because of a problem with your wound, other than at a routine planned follow-up appointment?	461	85.90	61.77	0.6312
6	Has the wound been smelly?	454	97.43	93.72	0.5911
3b	Was it blood-stained fluid? (haemoserous exudate)	89	86.74	68.55	0.5784
4a)	Did the skin separate?	56	88.56	74.57	0.5501
8	Have you had, or felt like you have had, a raised temperature or fever? (fever >38^{o}C)	454	94.93	89.44	0.5203
13	Have the edges of your wound been deliberately separated by a doctor or nurse?	456	96.93	93.64	0.5175
3c	Was it thick and yellow/green fluid (pus/purulent exudate)	71	84.68	68.47	0.5143
11	Have you been back into hospital for treatment with a problem with your wound?	437	95.65	91.06	0.5138
2	Was the area around the wound warmer than the surrounding skin?	454	89.06	79.75	0.4597
1	Was there redness spreading away from the wound? (erythema/cellulitis)	463	87.47	78.18	0.4260

Item*		N	Observed agreement (%)	Expected agreement (%)	Weighted Kappa
15	Has your wound been drained? (drainage of pus/abscess)	445	97.08	94.94	0.4221
14	Has your wound been scraped or cut to remove any unwanted tissue? (debridement of wound)	454	98.68	97.82	0.3936
7	Has the wound been painful to touch?	462	84.34	74.96	0.3748
5	Has the area around the wound become swollen?	459	88.16	82.86	0.3092
16	Have you had an operation under general anaesthetic for treatment of a problem with your wound?	449	99.78	99.78	0.0000

*Items ordered in descending (highest to lowest) values of Kappa statistic. Values between 0.4 and 0.75 were considered to be fair to good agreement [46]

Notable observations in comparisons of responses

Signs and symptoms

Although responses in self- and observer assessments were similar, a trend for patients to report signs and symptoms a little more severely than healthcare professionals was observed. This is demonstrated in Figure 3-7, where the percentage of responses of 'not at all' and 'a little' differs slightly between self- and observer assessments. The difference, however, was small and not significant.

'Major' wound care interventions

Data showed that the more 'major' wound care interventions, that is, interventions that required a degree of surgical intervention such as wound debridement, deliberate reopening, and the need for draining or reoperation

(assessed by Items 13 to 16) were rare in the study sample. Reports that these interventions had occurred were as low as 1-3%. Although these interventions were rare, examination of the raw data showed that there was slight discrepancy in agreement between self- and observer reports of whether they had occurred (Table 3-19). For example, six patients reported that their wound had been scraped or cut to remove unwanted tissue (item 14), however only 2/6 (33.3%) of the observer's assessment agreed (that is, the healthcare professional agreed with the patient that the intervention had occurred). Conversely, observer assessments reported that two patients had had their wound scraped or cut to remove unwanted tissue which was not indicated by the patient themselves (that is, the patient disagreed with the healthcare professional that the intervention had occurred). This suggests a degree of misunderstanding or lack of awareness of these interventions for a very low number of participants.

Table 3-19: Comparison of participant and HCP agreement for reports of 'major' wound care interventions

Item		Participant reported that intervention had occurred n	HCP report agreed that intervention had occurred n (%)
13	Have the edges of your wound been deliberately separated by a doctor or nurse?	14	8 (57.1%)
14	Has your wound been scraped or cut to remove any unwanted tissue? (debridement of wound)	6	2 (33.3%)
15	Has your wound been drained? (drainage of pus/abscess)	16	5 (31.3%)
16	Have you had an operation under general anaesthetic for treatment of a problem with your wound?	1	0 (0.0%)

3.5.5. Construct validity

Initial examination of item correlations

Correlations of responses for all pairs of items and sub-items to identify potential item redundancy are provided in Appendix 19. A very high correlation (0.94 in participant self-assessment data) was observed between Item 4 and the sub-item 4a. These were "Have the edges of any part of the wound separated/gaped open on their own accord? (spontaneous dehiscence)" and "Did the skin separate?". An examination of the raw data confirmed that participants' responses to these items were identical for almost all respondents. The issues intended to be measured by these two items were reconsidered by the study team, and it was recognised and agreed that they were addressing the same thing. Question 4a was therefore deemed redundant and excluded in further analysis of the scale structure.

Multi-trait scaling analysis

Two *a priori* hypotheses for the scale structure of the new SSI measure were proposed, as described in the methods (Chapter 2). These were a unidimensional construct (single scale) and a multi-dimensional construct (consisting of four multi-item scales and two single items, informed by clinical and expert knowledge).

First, the single scale model was tested in data from the cohort study, separately for data from self- and observer assessments. Item-scale correlations are reported in Table 3-20. Values above 0.30 suggested substantial correlation, as described in the study methods [84]. Results supported convergence of items to a single scale with the majority of item-scale correlations ranging between 0.31 and 0.75. The exceptions were four

items (two items assessing signs/symptoms of swelling and pain in data from self-assessments, and two items assessing the wound care interventions debridement and reoperation in data from self- and observer-assessments). For these items, item-scale correlations were between 0.07 and 0.23 (that is, below the 0.30 threshold for an acceptable correlation [84]). The low correlation values for the items assessing debridement and reoperation may be explained by the very low number of cases occurring in the dataset (<n=4 in the cohort study data) rather than a poor fit of a single scale model.

Next, the multi-scale model (four multi-item scales and two single items) was tested. Item-scale correlations are reported in Appendix 20 (self-assessment data) and Appendix 21 (observer data). Convergence of items to their hypothesised scales was supported, with item-scale correlations ranging between 0.24 and 0.73 (self-assessment data), with only one exception (Item 16, with an item-scale correlation of 0.05). There was, however, weak evidence for item discrimination. Correlations between items and their hypothesised scales were similar to correlations with other scales in the model, providing low evidence to suggest that more than one scale exists [86]. Data showed Item 1, for example, had item-scale correlations of 0.42, 0.32, 0.40 and 0.31 across the four hypothesised scales (self-assessment data).

Table 3-20. Multi-trait scaling: item-scale correlations for a single scale structure (cohort study data).

		Patient self-assessment (n=304)	Observer assessment (n=311)
	Number of items in scale	20	20
	Cronbach alpha co-efficient	0.83	0.86
Item*		**Item-scale correlation**	**Item-scale correlation**
3	Was any part of the wound leaking fluid?	0.74	0.75
3b	Was it blood-stained fluid? (haemoserous exudate)	0.67	0.58
12	Have you been given antibiotics for a problem with your wound?	0.61	0.64
9	Have you sought advice because of a problem with your wound, other than at a routine planned follow-up appointment?	0.58	0.59
4	Have the edges of any part of the wound separated/gaped open on their own accord? (spontaneous dehiscence)	0.55	0.66
3c	Was it thick and yellow/green fluid (pus/purulent exudate)	0.52	0.59
1	Was there redness spreading away from the wound? (erythema/cellulitis)	0.50	0.59
11	Have you been back into hospital for treatment with a problem with your wound?	0.49	0.41
3a	Was it clear fluid? (serous exudate)	0.48	0.30
4b	Did the deeper tissue separate?	0.46	0.46
15	Has your wound been drained? (drainage of pus/abscess)	0.38	0.31
2	Was the area around the wound warmer than the surrounding skin?	0.37	0.54
10	Has anything been put on the skin to cover the wound? (dressing)	0.36	0.47
13	Have the edges of your wound been deliberately separated by a doctor or nurse?	0.33	0.41
6	Has the wound been smelly?	0.32	0.39
8	Have you had, or felt like you have had, a raised temperature or fever? (fever >38^{o}C)	0.31	0.44
5	Has the area around the wound become swollen?	0.23	0.37
14	Has your wound been scraped or cut to remove any unwanted tissue? (debridement of wound)	0.17	0.21
7	Has the wound been painful to touch?	0.16	0.31
16	Have you had an operation under general anaesthetic for treatment of a problem with your wound?	0.07	(no observations)

*Items are ordered in descending (highest to lowest) values of item-scale correlation for participant self-assessment data

Factor analysis

Exploratory factor analysis was performed as an alternative, second statistical approach to examine construct validity. As described in the methods (Chapter 2), a second statistical approach was undertaken i) to explore whether items clustered together in a way that had not been hypothesised *a priori* and therefore could not be tested using multi-trait scaling and, ii) for methodological interest (to compare the findings of multi-trait scaling and factor analysis) for exploring the dimensionality of the data.

Data from both participant self-assessments and observer assessments fitted a single scale model satisfactorily (Table 3-21). Item factor loadings were positive for all items, with the majority with values ranging between 0.30 and 0.87. The exceptions were four items (two items assessing swelling and pain in data from self-assessments, and two items assessing debridement and reoperation in data from self- and observer-assessments), identical to the results from the multi-trait scaling analysis. Data for these items did not fit the single scale model well (demonstrated by low factor loadings of less than 0.27) or were dropped from the model by the software because of a lack of variability in the data (meaning too few participants in the dataset reported that these interventions had occurred and therefore it was not possible to include these items in the model). In general, item factor loadings were higher in data from the observer assessments compared to data from the self-assessments, indicating that, although both data fitted the single scale model well, the observer data fitted the single scale model even more satisfactorily.

There was no evidence from the exploratory analysis to support a two or three factor model in favour of a single factor model. Parameters from a three-factor model are provided in Appendix 22 (self-assessment data) and

Appendix 23 (observer data). Eigenvalues indicated that a single factor explained most of the variance in the data [86].

Table 3-21. Factor loadings for a single factor model, ml method of estimation (cohort study data)

		Patient self-assessment (n=201)	Observer assessment (n=299)
	Eigenvalue	4.67	5.09
Item*		Item-factor loading	Item-factor loading
3	Was any part of the wound leaking fluid?	0.8685	0.8110
3b	Was it blood-stained fluid? (haemoserous exudate)	0.7467	0.6262
12	Have you been given antibiotics for a problem with you wound?	0.6599	0.6845
9	Have you sought advice because of a problem with your wound, other than at a routine planned follow-up appointment?	0.5934	0.5963
4	Have the edges of any part of the wound separated/gaped open on their own accord? (spontaneous dehiscence)	0.5620	0.6980
3a	Was it clear fluid? (serous exudate)	0.5127	0.3917
15	Has your wound been drained? (drainage of pus/abscess)	0.5106	0.3289
11	Have you been back into hospital for treatment with a problem with your wound?	0.5028	0.3712
4b	Did the deeper tissue separate?	0.4837	0.5110
3c	Was it thick and yellow/green fluid (pus/purulent exudate)	0.4642	0.6368
6	Has the wound been smelly?	0.4456	0.3524
1	Was there redness spreading away from the wound? (erythema/cellulitis)	0.4178	0.6425
13	Have the edges of your wound been deliberately separated by a doctor or nurse?	0.4134	0.3891
10	Has anything been put on the skin to cover the wound? (dressing)	0.4072	0.5158
8	Have you had, or felt like you have had, a raised temperature or fever? (fever >38^{o}C)	0.2962	0.4221
14	Has your wound been scraped or cut to remove any unwanted tissue? (debridement of wound)	0.2894	0.0426
7	Has the wound been painful to touch?	0.2701	0.3063
2	Was the area around the wound warmer than the surrounding skin?	0.2234	0.5743
5	Has the area around the wound become swollen?	0.1724	0.3231
16†	Have you had an operation under general anaesthetic for treatment of a problem with your wound?	-	-

† Model dropped this item because of zero variance (self-assessment data) and collinearity (observer data; all scores were equal to zero)

*Items are ordered in descending (highest to lowest) values for item-factor loading for participant self-assessment data

Summary of findings for construct validity (multi-trait scaling and factor analyses)

Overall, examination of the data using both multi-trait scaling and factor analysis techniques supported a unidimensional (single) scale for measuring the underlying construct of SSI. This made clinical and practical sense. Findings meant that a simple approach to scoring the new measure could be taken, adding scores for responses to all of the items together to provide a single overall total score.

Validation of the scale structure

As a method of independent validation for the single scale structure determined from the cohort study data, the single factor model was applied to data from the pilot RCT to test for replicability of good fit. Evidence for a good fit was even stronger in the RCT data than the cohort study data, with generally higher item factor loadings (Appendix 24). Findings, therefore, supported a single scale model, validating the unidimensional structure of the SSI measure.

The single scale model was finally applied to the entire dataset (cohort study and pilot RCT data combined). Parameters are shown in Table 3-22. Evidence of fit was even stronger with the combined data, with factor loadings all above 0.30 and most 0.4 or higher. The exception was for Item 14 assessing debridement (in data from the observer assessment) with an item factor loading of 0.03. As described earlier, this is likely to be explained by the low number of observations in the dataset rather than a poor fit of data to the model.

Table 3-22. Factor loadings for a single factor model, ml method of estimation (combined cohort study and pilot RCT data)

		Patient self-assessment (n=362)	Observer assessment (n=501)
	Eigenvalue	5.26	5.08
Item*		Item-factor loading	Item-factor loading
3	Was any part of the wound leaking fluid?	0.8681	0.8503
3b	Was it blood-stained fluid? (haemoserous exudate)	0.7183	0.5804
4	Have the edges of any part of the wound separated/gaped open on their own accord? (spontaneous dehiscence)	0.6769	0.6317
12	Have you been given antibiotics for a problem with you wound?	0.6536	0.6746
9	Have you sought advice because of a problem with your wound, other than at a routine planned follow-up appointment?	0.6133	0.5854
4b	Did the deeper tissue separate?	0.5875	0.4291
3c	Was it thick and yellow/green fluid (pus/purulent exudate)	0.5731	0.6398
3a	Was it clear fluid? (serous exudate)	0.5654	0.4504
6	Has the wound been smelly?	0.4864	0.4268
1	Was there redness spreading away from the wound? (erythema/cellulitis)	0.4528	0.6557
11	Have you been back into hospital for treatment with a problem with your wound?	0.4513	0.3485
10	Has anything been put on the skin to cover the wound? (dressing)	0.4186	0.5364
13	Have the edges of your wound been deliberately separated by a doctor or nurse?	0.4068	0.4012
8	Have you had, or felt like you have had, a raised temperature or fever? (fever >38^{o}C)	0.3946	0.3898
15	Has your wound been drained? (drainage of pus/abscess)	0.3820	0.3338
7	Has the wound been painful to touch?	0.3635	0.3697
14	Has your wound been scraped or cut to remove any unwanted tissue? (debridement of wound)	0.3368	0.0324
2	Was the area around the wound warmer than the surrounding skin?	0.3173	0.5637
5	Has the area around the wound become swollen?	0.3159	0.3589
16†	Have you had an operation under general anaesthetic for treatment of a problem with your wound?	-	-

† Model dropped this item because of collinearity

*Items are ordered in descending (highest to lowest) values for item-factor loading for participant self-assessment data

Sensitivity analysis: factor analysis with a polychoric matrix

Factor analysis with a polychoric matrix was run as a sensitivity analysis to account for skewed categorical data. Similar to the item-item correlation matrix using Pearson's coefficients, the polychoric matrix for patient data showed a very high correlation (0.99) between item 4 and the sub-item 4a suggesting high overlap of these items (Appendix 25). Sub-item 4a was, therefore, excluded from the polychoric factor analysis. In addition, the software also removed items 14 and 16 from the polychoric matrix (due to the very low number of observations for these wound care interventions in the dataset meaning values could not be computed). Polychoric factor analysis supported the standard factor analyses, demonstrating a good fit of the data to a single factor model with high factor loadings (all above 0.42) (Appendix 26).

Internal consistency of the scales

The internal consistency of the single SSI scale was good. Cronbach's alpha coefficients using combined cohort study and pilot RCT data (excluding sub-item 4a) were high, with values of 0.86 and 0.88 in participant and observer data, respectively.

3.5.6. Criterion validity

Reference SSI assessments determined by face-to-face assessment of the wound using the CDC criteria were completed for 417/792 (53.0%) participants: 115/414 (27.8%) participants in the cohort study and 302/378 (79.9%) participants in the pilot RCT. As explained in the methods (Chapter 2), a subset of participants were invited for a reference assessment in the cohort study, whereas all participants in the pilot RCT were invited for a reference assessment. Reference assessments were made a median of 44 days (inter-quartile range 36 to 52 days) after surgery.

Plotting the ROC curve

To plot the ROC curve, first participant self-assessment total scores for the new outcome measure were calculated. A total score was derived by adding the scores of responses to the individual items without any item weightings, demonstrated to be appropriate from the analysis of the scale structure. This excluded sub-item 4a that was deemed redundant due to item overlap (see earlier, section 3.5.5). A possible total score could range from 0 to 44. Actual total scores in the self-assessment data ranged between 0 and 30.

Cross-tabulations of total scores against the dichotomous reference assessment of 'SSI of any type' or 'no SSI' were examined (Table 3-23). Sensitivity and specificity values were calculated for different levels (thresholds) of cut-off score on the new measure (Table 3-24) and used to plot the ROC curve. Findings showed the sensitivity and specificity of the self-assessment score for discriminating between individuals who had had an SSI

of any type and those who had not had an SSI was high, with an area under the ROC curve of 0.906 (95% confidence interval 0.827 to 0.984) (Figure 3-8). From the current data, a cut-off score around 6 to 8 appeared to be a reasonable threshold for suggesting SSI / no SSI compared with the reference assessment, with relatively few misclassifications.

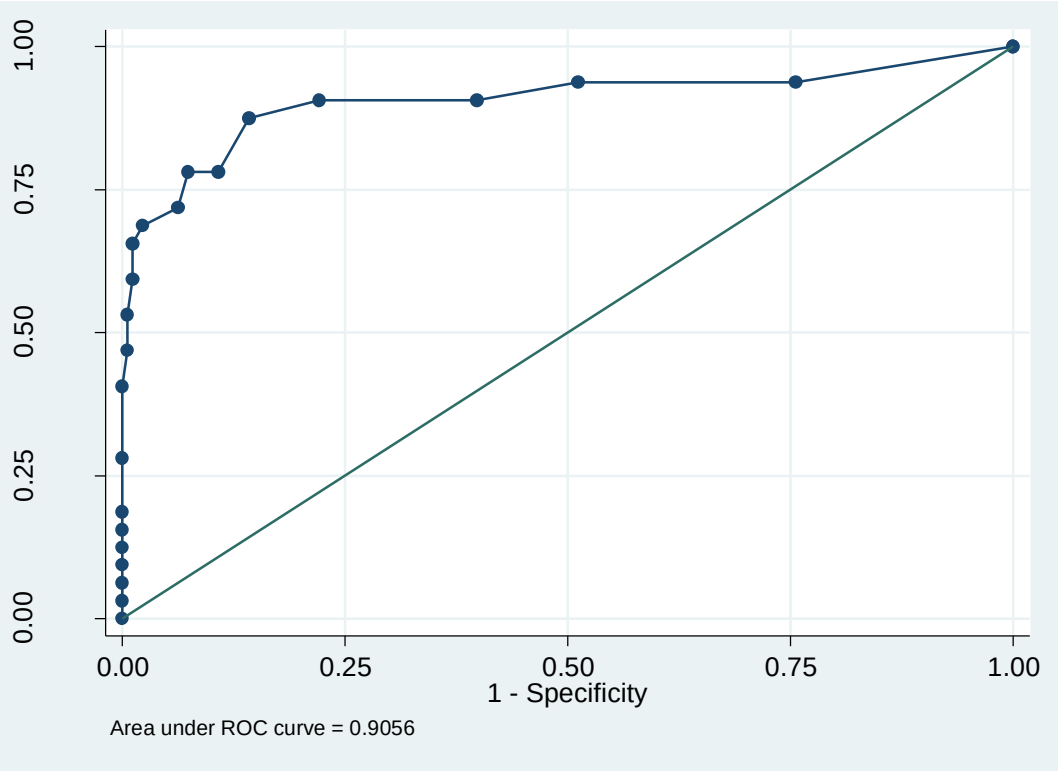
Table 3-23. Tabulation of participant self-assessment total score against the reference SSI assessment

Self-assessment total score	**Reference diagnosis** (no. of participants)		**Total number of participants**		
	No SSI	SSI of any type	(n)	%	cumulative %
0	43	2	45	21.6%	21.6%
1	43	0	43	20.7%	42.3%
2	20	1	21	10.1%	52.4%
3	31	0	31	14.9%	67.3%
4	14	1	15	7.2%	74.5%
5	6	3	9	4.3%	78.8%
6	6	0	6	2.9%	81.7%
7	2	2	4	1.9%	83.7%
8	7	1	8	3.8%	87.5%
9	2	1	3	1.4%	88.9%
10	0	2	2	1.0%	89.9%
11	1	2	3	1.4%	91.3%
12	0	2	2	1.0%	92.3%
13	1	2	3	1.4%	93.8%
15	0	4	4	1.9%	95.7%
17	0	3	3	1.4%	97.1%
18	0	1	1	0.5%	97.6%
19	0	1	1	0.5%	98.1%
20	0	1	1	0.5%	98.6%
26	0	1	1	0.5%	99.0%
28	0	1	1	0.5%	99.5%
30	0	1	1	0.5%	100.0%
Total	**176**	**32**	**208**	**100%**	**100.0%**

Table 3-24. Sensitivity and specificity for incremental cut-off values in the self-assessment total score against the reference SSI assessment

Total score cut-off threshold	**Sensitivity** (%)	**Specificity** (%)	**Correctly classified** (%)
>= 0	100.00	0.00	15.38
>= 1	93.75	24.43	35.10
>= 2	93.75	48.86	55.77
>= 3	90.63	60.23	64.90
>= 4	90.63	77.84	79.81
>= 5	87.50	85.80	86.06
>= 6	78.13	89.20	87.50
>= 7	78.13	92.61	90.38
>= 8	71.88	93.75	90.38
>= 9	68.75	97.73	93.27
>= 10	65.63	98.86	93.75
>= 11	59.38	98.86	92.79
>= 12	53.13	99.43	92.31
>= 13	46.88	99.43	91.35
>= 15	40.63	100.00	90.87
>= 17	28.13	100.00	88.94
>= 18	18.75	100.00	87.50
>= 19	15.63	100.00	87.02
>= 20	12.50	100.00	86.54
>= 26	9.38	100.00	86.06
>= 28	6.25	100.00	85.50
>= 30	3.13	100.00	85.10
> 30	0.00	100.00	84.62

Figure 3-8. Receiver operating characteristic (ROC) curve for participant self-assessment total score for discriminating SSI compared to the reference SSI assessment



3.5.7. Modifications for producing the final measure (version 3.0)

Evidence from the acceptability, reliability and validity analyses described above were considered by the study team. This led to further modifications of the measure to produce a version ready for use in future studies (version 3.0). These modifications are listed in Table 3-25. In summary, modifications were: 1) dropping one sub-item due to overlap; 2) restructuring three former sub-items as main items; and 3) dropping one further item due to redundancy (as

a result of the restructuring of sub-items). The final items and their response categories following these modifications, ready for use in future studies, are shown in Table 3-26. The full final version of the measure formatted as a questionnaire is provided in Appendix 27.

Table 3-25. Modifications for the final version of the SSI measure after field-testing

Modification number	Item/sub-item in version 2.0	Modification for version 3.0	Reason for modification
1	Sub-item 4a "Did the skin separate?"	Sub-item dropped	Tests for construct validity and examination of raw data demonstrated substantial overlap with preceding item 4 "Have the edges of any part of the wound separated/gaped open on their own accord? (spontaneous dehiscence)".
2	Sub-items 3a "Was it clear fluid? (serous exudate)" 3b "Was it blood-stained fluid? (haemoserous exudate)" 3c "Was it thick and yellow/green fluid (pus/purulent exudate)"	Reformatted and rephrased as standalone items (rather than sub-items) for all respondents to complete. Items renumbered accordingly.	High levels of missing data where a response would have been expected suggested problems with formatting / layout of the questionnaire and/or respondent misunderstanding of whether sub-items should have been completed.
3	Item 3 "Was any part of the wound leaking fluid?"	Item dropped	Item now redundant due to modification 2

Table 3-26. Items and response categories in the final version of the SSI measure after analysis

	Item	Response categories
1	Was there redness spreading away from the wound? (erythema/cellulitis)	Not at all / A little / Quite a bit / A lot
2	Was the area around the wound warmer than the surrounding skin?	Not at all / A little / Quite a bit / A lot
3	Has any part of the wound leaked clear fluid? (serous exudate)	Not at all / A little / Quite a bit / A lot
4	Has any part of the wound leaked blood-stained fluid? (haemoserous exudate)	Not at all / A little / Quite a bit / A lot
5	Has any part of the wound leaked thick and yellow/green fluid (pus/purulent exudate)	Not at all / A little / Quite a bit / A lot
6a	Have the edges of any part of the wound separated/gaped open on their own accord? (spontaneous dehiscence)	Not at all / A little / Quite a bit / A lot
	(Subitem 6b): Did the deeper tissue separate?	Not at all / A little / Quite a bit / A lot
7	Has the area around the wound become swollen?	Not at all / A little / Quite a bit / A lot
8	Has the wound been smelly?	Not at all / A little / Quite a bit / A lot
9	Has the wound been painful to touch?	Not at all / A little / Quite a bit / A lot
10	Have you had, or felt like you have had, a raised temperature or fever? (fever >38^{o}C)	Not at all / A little / Quite a bit / A lot
11	Have you sought advice because of a problem with your wound, other than at a routine planned follow-up appointment?	Yes / No
12	Has anything been put on the skin to cover the wound? (dressing)	Yes / No
13	Have you been back into hospital for treatment with a problem with your wound?	Yes / No
14	Have you been given antibiotics for a problem with you wound?	Yes / No
15	Have the edges of your wound been deliberately separated by a doctor or nurse?	Yes / No
16	Has your wound been scraped or cut to remove any unwanted tissue? (debridement of wound)	Yes / No
17	Has your wound been drained? (drainage of pus/abscess)	Yes / No
18	Have you had an operation under general anaesthetic for treatment of a problem with your wound?	Yes / No

Reflections on other notable observations and justification for not implementing them in revisions to the measure

More than 90% of participants reported that their wound had not been smelly at all (item 6). Similarly, 85% of patients reported that they had not had, or felt like they had had, a raised temperature or fever (item 8). Item-scale correlations and factors loadings for these items in a single scale structure were moderate. The study team considered the importance of these items for SSI diagnosis and whether they should remain included in the measure. A conservative approach was taken to keep them included, to enable them to be examined further in future studies where these symptoms may be more prevalent in other patient groups and surgical specialties.

Item 14 ("Has your wound been scraped or cut to remove any unwanted tissue?") and item 16 ("Have you had an operation under general anaesthetic for treatment with a problem with your wound?") were shown to be very rare interventions in this dataset, with only 1% of the study sample reporting that these interventions had occurred. However, due to the high clinical relevance of these intervention for determining whether SSI has occurred, and because they may be more frequent in different surgical populations, the study team decided not to exclude these items.

3.6. Discussion

This chapter has reported the findings from the development and validation of a new outcome measure for SSI. It describes the results of tests for content, construct and criterion validity, reliability and acceptability. First, content validity was addressed by i) a content analysis of the most commonly used tools for assessing SSI (two clinical tools and two unvalidated questionnaires for patients) and ii) an analysis of data from 19 interviews with patients and healthcare professionals. Some 19 important content domains to include in the new measure were identified. Next, content validity and acceptability were further addressed in 42 cognitive interviews to pre-test the new outcome measure.

Pre-testing and revisions were conducted as an iterative process, producing a version of the new measure ready for further validation. Findings from a large field-testing study including data from 792 participants are reported. The measure was found to be acceptable to patients and demonstrated good response rates, with low levels of missing data. Analyses supported a single-scale structure to assess SSI that made clinical and practical sense. Test–retest reliability was high, and agreement between participants and observers was good. The measure demonstrated high sensitivity and specificity for SSI discrimination compared with a face-to-face reference SSI assessment using the CDC criteria.

3.6.1. Strengths

Established and widely used methodology was applied for the development and validation of the new outcome measure. An existing framework and recommended methods to identify develop, pre-test and field-test the measure were applied to address content, construct and criterion validity and reliability [85,89]. The study included mixed methodology to add strength to the development of the measure. For example, synthesising findings from qualitative interviews and a content analysis of existing tools to identify the important content domains [85]. Further methodological strengths for this study include the purposive sampling of participants with experience of SSI to ensure that the views of all key stakeholders were considered in the development of the measures [46]. The perspectives of patients, surgeons, GPs and nurses were all considered. Rigorous pre-testing, again with both patients and healthcare professionals, was undertaken to ensure face and content validity with relevance to future stakeholders. The inclusion of a wide range of abdominal operations provided a diverse sample, adding strength to the generalisability of the findings. A further methodological strength of this study is the approach used to analyse data. Two statistical approaches, multi-trait scaling and factor analysis, were taken to examine construct validity and explore the underlying scale structure [86]. A method of independent validation was applied by splitting the dataset (cohort study versus pilot RCT data) and testing replicability of the most suitable model identified. A sensitivity analysis was also performed using polychoric data. The concordant results from these approaches strengthen the finding that the outcome measure appropriately measures SSI with a single scale allowing for a simple scoring system that makes clinical and practical sense. The original intention

for developing the outcome measure was for the assessment of SSI in the context of an outcome in clinical trials. During the course of the PhD work, it has become apparent that the tool could be used for additional purposes, such as a screening tool to warrant a face to face assessment of the wound and the need for further treatment. This is discussed in more detail in the Discussion chapter. An alternative scale structure, for example, that separates items that assess 'symptoms of infection' and items that assess 'management/treatment' may be useful in this context and warrants further research.

A total of 19 participants were interviewed to inform the content of the new measure. The issue of sample size in qualitative studies is a long-standing topic of debate, with qualitative sample sizes often criticised as being too small and under-representative [116]. Interviews, however, provide a rich data source because they allow for detailed, contextual information to be collected. Best practice is to interview a number of participants until data saturation is reached, that is, no new themes are identified from subsequent interviews [109]. The current study adhered to these recommendations and participants were interviewed until no new SSI domains were identified. To ensure methodological rigour of the study methods and any potential limitation of a relatively small qualitative sample, synthesis of data from the content analysis of existing SSI tools was performed. This increased the confidence that all important domains had been identified.

3.6.2. Limitations

Identification of important domains: content analysis of existing tools for measuring SSI

The Bruce et al. systematic review of existing SSI definitions and grading scales was conducted nearly 20 years ago [31]. Based on a scoping search conducted at the start of this PhD, a formal update of the full systematic review was not performed. This may mean that some tools exist that have not been identified. This, however, is unlikely. As described earlier in this chapter, evidence that the tools identified in the Bruce et al. review were still the most commonly used tools in the field is demonstrated in recent Cochrane reviews of studies of interventions to reduce SSI [20,117]. This is further supported with empirical evidence based on the practices of PHE [34], NICE quality standards [118] and expert knowledge from within research networks such as WReN and the NWCSP, as . Although the tools selected for the content analysis (the CDC diagnostic criteria and the ASEPSIS grading scale) have limitations as previously described in Chapter 1, they are supported in the field as the most comprehensive for diagnosing SSI. Other criteria and grading scales do exist, as identified in the Bruce et al. 2001 review, although these are not widely used and have not been validated [31]. They are comprised of similar but fewer SSI domains compared to the CDC criteria and ASEPSIS grading scale [11]. It was considered that a content analysis of these other tools, therefore, would not have added any further value to the study.

Identification of important domains: interviews with patients

It is recognised that only two of the nine patient participants interviewed were confirmed to have had an SSI (one participant had suspected wound infection, two had no infection and four had missing data on wound infection). Collection and completeness of these data by the author of this thesis was not possible as it occurred during a period of maternity leave. However, this was not considered to be a significant limitation as data were synthesised with domains from existing SSI tools as well as interviews with healthcare professionals.

Analysis of the measurement properties

The evaluation of the measurement properties of the new outcome measure is limited, to date, to the current dataset and study sample. Reports of more major wound care interventions (such as debridement and drainage) were very rare and this may have had an impact, for example, on analyses of the scale structure. It is unknown how a dataset with higher frequencies of these types of wound care interventions may affect the item correlations and subsequently the underlying scale structure. Data from other studies and independent samples are needed for further validation and to see how the measure performs in different populations. This work has been started and will be described in more detail in Chapter 6 (section 6.7 'Future research'). Whilst being aware that other statistical techniques are available to shrink or attenuate performance statistics to compensate for same sample data ("shrinkage") [112], the use of these techniques were not applied in the current study. Instead, there was an opportunity to split the sample to validate the scale structure of the measure. The initial analysis was performed

in half the dataset, including only participants from the cohort study (n=414 participants). The scale structure was then applied to data from the pilot RCT (n=378 participants). This was considered to be a suitable independent validation technique for the purpose of the current study with adequate sample sizes for the validation of outcome measures [109].

The validation study used recommended statistical methods to examine construct validity and the underlying scale structure of the new outcome measure, specifically factor analysis and multi-trait scaling [46]. These statistical methods are widely used in the development and validation of similar outcome measures such as quality of life questionnaires [46,86]. The methods, however, were primarily developed for continuous data and have recognised limitations when applied to the type of data derived from questionnaires with categorical responses [86]. To address these limitations, the current study chose to apply both factor analysis and multi-trait scaling and to compare the findings. The scale structure was supported by both statistical approaches. In addition, a sensitivity analysis using polychoric data was conducted. Again, findings supported a single scale.

Some discrepancy was observed between participant and healthcare professional reports of the more 'major' wound care interventions. For example, 16/445 (3.6%) participants self-reported that their wound had been drained. Of these, only 5/16 (31.3%) healthcare professional reports (observer assessments) agreed that this intervention had occurred. Although very few examples of this were apparent in the current data, this may be important for the reliability of the measure for patient self-report, as it suggests possible low

fidelity of participant responses to these items. This discrepancy may be important to consider and warrants further investigation in other datasets. It may, for example, have implications for studies relying solely on patient self-assessment for collecting outcome data. A limitation of the current study is that these wound care interventions were very rare in the dataset, making it difficult to know the scale of this discrepancy in participant and observer reports in a sample where these interventions were more frequent.

A further limitation to the analysis of the measurement properties is in relation to criterion validity. The selected reference standard for SSI was a face-to-face assessment of the wound using the CDC criteria. This was chosen as the best available reference standard for comparing scores on the outcome measure as it is the most commonly used and widely regarded method for diagnosing SSI [20,31]. Despite this, the CDC criteria still require a degree of subjective judgement from the person making the assessment. A gold standard diagnosis of SSI, without subjective bias, is lacking, meaning tests of criterion are limited [113]. The use of the CDC as the reference assessment in this study also introduces an element of circularity to the data analysis. The content of the new outcome measure was largely derived from the CDC criteria used to define SSI. It could be argued, therefore, that a good ROC curve result (that is, the ability of the new measure to discriminate between SSI and no SSI) using a CDC diagnosis as the reference standard is not surprising. Without a 'better' or true standard as alternative comparator, tests for criterion validity are subject to these limitations [113].

Mode of administration

Current validation of the new outcome measure is limited to its use as a postal questionnaire. It is unknown whether an alternative method of administration, such as an electronic version of the measure, may have an impact on the findings. For example, higher or lower response rates may have been achieved. The mode of administration (that is, postal or electronic) may introduce bias into the study population by inadvertently selectively sampling participants from a specific demographic, for example, older or younger ages. This could have implications for the analysis if there is an association between the participant characteristics and the study outcome of fewer or more wound problems. The new outcome measure is suitable for conversion to electronic data collection. An electronic version allows forced item completion and has benefits to data collection by improving convenience and reducing missing responses to individual items [119]. Items from the new outcome measure were included in the online survey in the evaluation phase of the method for obtaining digital images from patients (Study 2). This was for exploratory purposes only and formal validation of the outcome measure in an electronic format was not an intended aim of the study. Further work to examine this is warranted.

The next chapters in this thesis now turn to the second study in this PhD research. This is the development and evaluation of a method intended to be complementary to the new outcome measure, for improving the assessment of SSI after patients leave hospital. The method focuses on the use of digital images, taken and transmitted by patients themselves, for remote wound assessment.

CHAPTER 4. METHODS: STUDY 2

DEVELOPMENT AND EVALUATION OF A METHOD FOR REMOTE WOUND ASSESSMENT USING PATIENT-GENERATED DIGITAL IMAGES

4.1. Introduction

The introductory chapter of this thesis (Chapter 1) described the purpose and value of digital images for assessing wounds. Whilst it is recognised that images are not sufficient on their own for SSI assessment because unobservable symptoms (for example, pain and heat) are important criteria, images can be used to enhance other data to improve diagnostic accuracy [70,120]. The use of patient-generated images for remote assessment of SSI has many potential benefits and is a growing area of interest in research and clinical practice [62,73,78].

Obtaining images from patients remotely comprises two steps. First, it requires patients to take a standardised image of their wound. Next it requires patients to transmit the image. Work to explore whether it is possible for patients to take and transmit a standardised wound image that is clinically

usable using their own mobile devices has not, however, been widely investigated. There is a need to explore whether a method for patients to take and transmit digital images of their wounds after leaving hospital using their own mobile device is feasible, acceptable and can provide images of sufficient quality for identifying SSI remotely.

This chapter describes the methods undertaken to develop and evaluate a method for obtaining patient-generated digital images after hospital discharge. The chapter begins by describing the rationale for the methodological approach taken, before stating the study aims and objectives. Next, it describes the development and pre-testing of the two necessary components to the method: 1) instructions for patients to take a standardised image of their wound using their own mobile device and 2) a process for patients to transmit the image to the study team. Finally, the chapter describes the methods used to evaluate the photography instructions and transmission process for potential use in a research or clinical context; testing to see whether they are feasible, usable, acceptable and ultimately able to provide an image that is suitable for SSI assessment after hospital discharge.

4.2. Aims and objectives of the current study

The aim of the current study was to develop and conduct an evaluation of a method for patient to take and transmit a standardised image of their wound for remote SSI assessment. The intention for the images was that they could supplement other patient-reported outcome data on signs, symptoms and

wound care interventions indicative of SSI, such as that collected by the SSI measure developed and validated as part of this PhD work (Chapters 2 and 3). Combined use of such data could optimise remote wound assessment for detecting and diagnosing SSI [70]. The use of patients' own mobile devices to take and transmit the images without the need to develop an app or new electronic platform was key to this study as discussed in Chapter 1, to minimise costs and resource use to maximise the potential widespread use of the method in the future.

Specific objectives of the study, as outlined in Chapter 1, were:

1) to develop a method for patients to take and transmit wound images:
    i) develop photography instructions for patients to take a standardised image of their wound after leaving hospital;
    ii) adapt existing IT software for patients to transmit wound images to a research/healthcare team using their own mobile device;
2) to pre-test and refine the method for taking and transmitting images with patients;
3) to examine the feasibility, usability and acceptability of the method taking and transmitting images with a large sample of patients after having surgery, including an examination of image quality.

It was recognised at the outset that fulfilment of the study objectives would enable the initial evaluation the method to be achieved. An evaluation of feasibility, usability, acceptability and image quality for intended use of the

method in a research or clinical setting was possible. Further testing of the method, to establish its feasibility and usability when an actual assessment of the wound for SSI is required (for example, for outcome assessment in a clinical trial or in routine surgical follow-up), was beyond the scope of this thesis.

4.3. Methodological framework for developing and evaluating a method for obtaining patient-generated images

4.3.1. Patients as photographers: smartphones and technologies

The increasing ownership of, or access to, personal mobile devices such as smartphones and tablet computers provides an opportunity to advance the field of wound assessment after the patient had left hospital, as described in Chapter 1. Firstly, the high proportion of these devices with built-in cameras provides an opportunity for patients to take digital images of their wounds. Secondly, the facility of these devices to access the internet provides an opportunity for digital transmission of the images to healthcare providers or researchers after leaving hospital. Guidelines and standard operating procedures (SOPs) on how to take a standardised image of a wound exist, for

example, for medical illustration departments in hospital trusts [77,121]. These have, however, primarily been developed for use by trained professionals (e.g. medical illustrators) using high-quality digital cameras in a clinical setting, such as a hospital wards or theatres. Guidelines that are suitable to instruct patients to take images of their wound using their own mobile device after leaving hospital are lacking.

There are multiple ways for patients to transmit images from mobile devices to healthcare teams or researchers, for example, via the internet to secure websites or servers [73]. As described in Chapter 1, mobile phone applications (apps) that allow patients to take and transmit digital images have been developed in the US and Europe specifically for remote monitoring of wounds for SSI surveillance [83]. Also described in Chapter 1, however, the development of such an app for obtaining images comes with a burden of cost and resource use implications. Other platforms besides apps, however, exist that allow the collection of data from patients at minimal cost to healthcare providers or researchers making them pragmatic for use in research and routine practice. Existing IT software systems, such as electronic databases with survey facilities, for example, are available and are frequently used in both research and clinical practice settings. Many have been designed to be easily accessible from a mobile device with internet access, providing the functionality to make them suitable for remote data collection after the patient has left hospital. There are some that provide a facility for uploading images, making them particularly suitable for the potential collection of wound images. An evaluation of the feasibility, usability and acceptability of such a system for patients to transmit wound images, however, needs to be

undertaken to ensure it is suitable for the remote collection of wound images after the patient has left hospital.

4.3.2. Rationale for methodological approach used

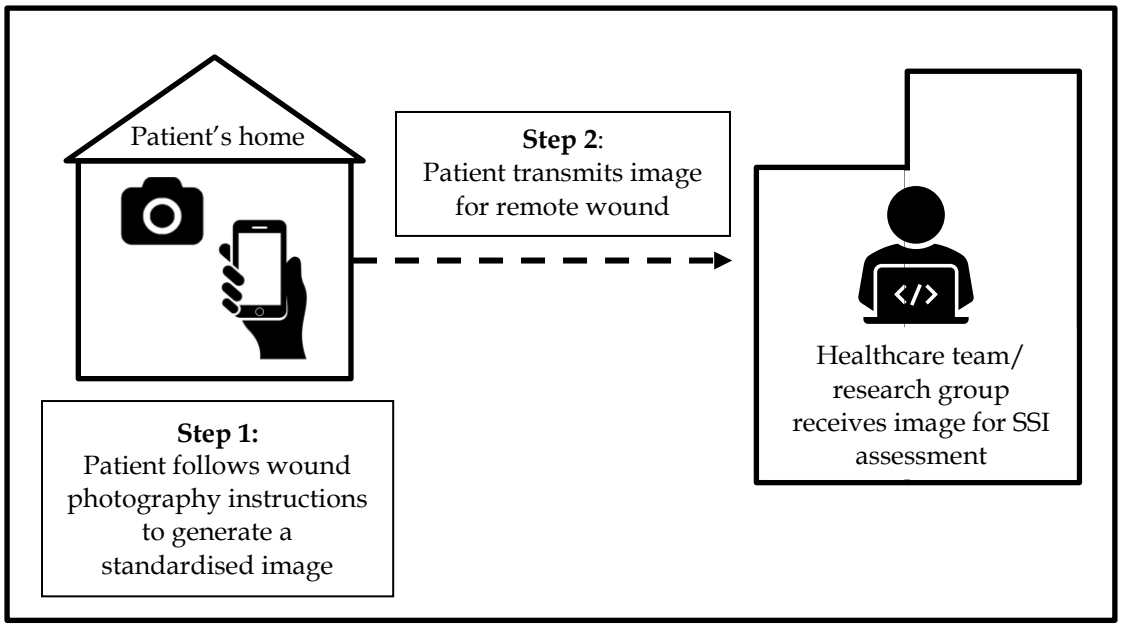
Two methodological approaches were utilised in the current study. Firstly, the approach drew on some of the principles for PROM development and validation (described in detail in the context of developing the new outcome measure in Chapter 2). This approach was chosen for several reasons. There was a need, for example, to address content validity of the photography instructions to ensure they included the necessary content for patients to take a standardised wound image. There was also a need to ensure that the instructions were comprehensible and acceptable to patients. These parallels with PROM development and validation, and the key properties being addressed, will be described in detail below. Secondly, the approach drew on some of the principles for developing and evaluating electronic systems for collecting data from patients. This approach was considered relevant due to the requirement for patients to use digital devices and technology to take and transmit wound images. Specifically, an evaluation of human-system interaction (usability) was undertaken. Evaluations of human-system interaction and tests of usability are an emerging methodological approach in the field of healthcare where established scientific methods for evaluating electronic data collection systems are lacking. Details of this methodological approach and the key properties being addressed will also be described further later in this chapter (section 4.7).

The use of the two methodological approaches in the current study had additional advantages for this PhD work. Firstly, it allowed for application and extension of the author's existing experience and knowledge of PROM development and validation to a novel context. Secondly, it provided an opportunity for developing knowledge and skills in the advancing field of digital health and an insight into suitable methods for their evaluation, such as tests of usability.

4.4. Study design and application of methodology

As described above, obtaining patient-generated images for remote wound assessment comprises two steps (Figure 4-1). First it requires patients to take and image of their wound, and secondly, it requires to transmit the image. Development of a method for obtaining images needs, therefore, two components to reflect these steps. These components were: 1) instructions for patients to take a wound photograph using their own mobile devices and 2) a process for patients to transmit the image.

Figure 4-1. Overview of the method for obtaining patient-generated digital images for remote wound assessment



The methods used in the current study were selected with consideration to the two methodological approaches, where relevant and available. Firstly, methods were selected to address content validity of the photography instructions for patients, to ensure they had the relevant content for patients to take a standardised image of the wound and that they were comprehensible and easy to follow [69]. Next, methods were selected to address feasibility; that is, to examine whether taking and transmitting wound images was practical and possible for patients to be able to do it [75,113]. Methods were applied to examine whether taking and transmitting images was effective and efficient; so that images can be obtained without problems and in a timely way without too much burden or need for extra resources [114]. Methods were also applied to address acceptability; that is, to

examine the appropriateness of the photography instructions and process for transmitting images so that patients were willing to do it [75]. Finally, methods were applied to assess the quality of the images received from patients, to examine whether they were suitable for potential SSI assessment remotely. Without rigorous methodology to ensure these key principles were met, future use of the method to obtain patient-generated wound images may be futile.

Phases of the study

Figure 4-2 shows how the study was broadly designed to be conducted in two consecutive phases to reflect the development and evaluation of the method for patient to take and transmit images of their wound. Figure 4-2 also details how the key principles of approaches to developing PROMs and evaluating human-system interactions were addressed in each phase.

Phase 1: Development and pre-testing

In Phase 1, the two components of the method for obtaining patient-generated images were developed and pre-tested. Specifically, Phase 1 involved:

i) an analysis of existing literature to identify important features for producing standardised wound images to inform photography instructions for patients,

ii) adaptation of an existing IT software system for patients to transmit images,

iii) one-to-one cognitive interviews with observation to pre-test and iteratively refine the photography instructions and process to transmit images.

Phase 2: Evaluation

In Phase 2, the separate components of the method developed and pre-tested in Phase 1 were combined and evaluated together. The feasibility, usability and acceptability of the complete method, and the quality of the wound images obtained, were examined. This included:

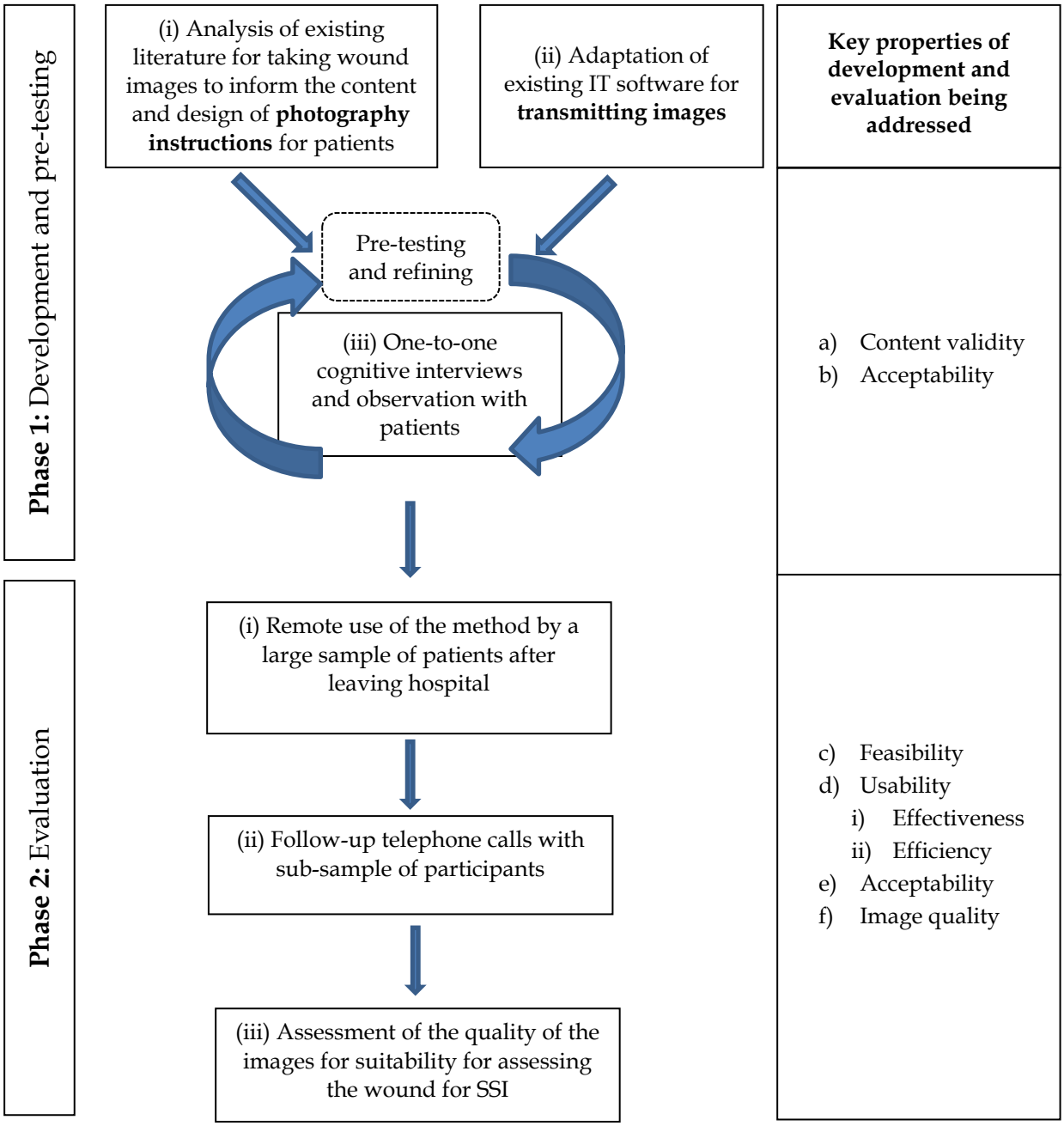
i) Remote (that is, at home; unsupervised) use of the method by a large sample of participants discharged home following surgery;

ii) Follow-up telephone calls with a sub-sample of patient participants;

iii) Reviewing the obtained images to assess their quality for SSI assessment.

A detailed description of the study methods follows in the rest of this chapter.

Figure 4-2. Development, pre-testing and evaluation of the method for obtaining patient-generated wound images: study phases, methods applied and key properties addressed



4.5. Patient and Public Involvement (PPI)

Patients and members of the public were consulted for advice to help design the study. The purpose of patient and public involvement (PPI) was to ensure that the research had relevance to patients and that the study would be as effective as possible, with the proposed methods and written information appropriate and acceptable to potential participants [122]. Before commencing the study, PPI work was conducted i) with a PPI group from an existing surgical feasibility study (the Bluebelle study [1]); and ii) on hospital wards talking to patients who had recently undergone surgery.

PPI members were consulted about the:

i) concept of the study and the aims and objectives

ii) content of the study participant information leaflet (PIL)

iii) preferred acronym for the study name from a list of options, for optimising recruitment and participation.

Views of the public were further sought as part of a public engagement event held at the Colston Hall in Bristol in May 2018. A small grant and opportunity to have a display stand at the Research without Borders festival was awarded to the author of this thesis following an application to be part of the event. The event was held prior to the start of recruitment to the study. Discussions with people during their visits to the stand provided an opportunity to present the study design and plans to members of the general public and to seek their views on the concept of the study, the feasibility and acceptability of taking and transmitting images of wounds after leaving hospital. This provided an opportunity to incorporate any suggestions before commencement of the study.

4.6. Phase 1 – Development and pre-testing

4.6.1. Objectives for Phase 1

The objectives for this phase of the study were:

- to develop a method for patients to take and transmit wound images:
    i) develop photography instructions for patients to take a standardised image of their wound after leaving hospital;
    ii) adapt existing IT software for patients to transmit wound images to a research/healthcare team using their own mobile device;
- to pre-test and refine the method for taking and transmitting images with patients.

4.6.2. Assessing content validity

Component 1: photography instructions for patients

An informal scoping search conducted in an electronic database of published medical literature (PubMed) and the internet by the author of this thesis identified no existing guidelines for developing instructions for patients to take wound images. In the absence of specific relevant guidelines for developing instructions for patients, the relevance of established methods for developing PROMs was considered. Methods for PROM development were considered relevant because the development of instructions for patients to

take a standardised wound photograph was deemed to involve several key principles likened to aspects of developing a new PROM.

Parallels with the principles of PROM development

Similar to a PROM, it was considered important that the photography instructions for patients included relevant content to ensure a suitable, standardised wound photograph was taken. The content of the instructions, therefore, needed to be informed by appropriate sources and they needed to be pre-tested to ensure they were acceptable, comprehensible and easy to follow. These principles are akin to the measurement property of content validity in PROM development [46]. Reflecting on these parallels with PROM development, it was chosen to adopt a similar methodological approach for the development of the photography instructions. The approach drew, therefore, on the first three phases of PROM development as described in the methods for Study 1 (Chapter 2). First, the important features for photographing a wound needed to be identified, much like the identification of important content domains for a new PROM [46,45]. This is required so that the image is standardised and of suitable quality for clinical use to assess the wound for SSI. Second, the identified features would need to be operationalised and drafted into instructions for patients to take an image using their own mobile devices, much like the operationalised of the important content domains into items in PROM development [85]. Finally, the instructions would require pre-testing with a sample of the target users and refining, where necessary, to ensure they were acceptable and fit for purpose [45,46,86].

i) Content analysis of existing literature

To address content validity of the photography instructions for patients, a content analysis of existing literature on how to take a wound photograph was performed. This was to ensure the important key features for taking a standardised image of a wound were identified, for consideration to include in the instructions for patients.

Sampling and identification of source documents

Sampling of existing literature on how to take standardised images of wounds for clinical purposes was undertaken, informed by a scoping search of published literature and expert knowledge within the study team and discussion with colleagues within the Wounds Research Network (WReN; within which the author of this thesis was involved, described in more detail later in this thesis; Chapter 6) and the Bristol Medical School. Of particular relevance, published guidance for professional medical illustrators taking images for clinical use in hospital settings was known to be available [77]. Studies of wound care interventions that used images for outcome assessment, and had wound photography protocols written for study personnel, were identified through discussion with colleagues. Further relevant documents describing wound photography were identified through a scoping search the of literature on the use of digital images in wound care, conducted by the author of this thesis. Due to the identification of source documents through these sampling methods, a systematic literature search for publications describing how to take standardised wound images was not considered necessary. This was because it was considered that the key features for taking a standardised photograph of the wound would be

included in sufficient detail in this identified sample of documents, in particular in the guidance for professional medical illustrators.

Obtaining source documents

Electronic versions of source documents were downloaded from relevant websites, where freely available. Further source documents, such as unpublished wound photography protocols for study personnel were obtained by request from the relevant study teams.

Data extraction

Source documents were scrutinised and any detail on how to prepare for, or take, a standardised wound image was extracted as verbatim text. Data extraction was broad to include any relevant information, with the intention to be as inclusive as possible so that subsequent analysis and identification of key features for taking standardised images was driven by the data, with no pre-determined framework influenced by the author of this thesis [91]. This approach ensured that all potentially relevant information on how to take a wound photograph could be considered for inclusion in the instructions for patients. Data were transcribed verbatim into a Microsoft Excel spreadsheet. Data extraction was performed by the author of this thesis.

Data analysis

Inductive, open coding of data was conducted, drawing on the approach for analysing data to identify content for PROM development [85]. Data were

organised into categories or groups based on the aspect of photography that they related to, for example, lighting or framing of the image. Categories were modified and adapted as more data was extracted in an iterative, inductive manner [91]. Categorisation of the data was reviewed and discussed with the study team to maximise robustness of the research and minimise subjectivity of the author when analysing data.

ii) Drafting the photography instructions

After grouping data into categories of the key features for taking a clear and standardised wound image, categories were examined for their relevance for including in photography instructions for patients. For the purpose of the study, it was necessary that the key features for photographing wounds were relevant to taking images after hospital discharge and using a camera on a mobile device. Relevant features were then formulated (operationalised) into an item (that is, an instruction) for a preliminary version of photography instructions for patients [46]. General information relevant to the instructions for patients was also drafted, explaining, for example, the overall objective of taking the wound image, the device that could be used, and that help from others to take the image was permitted, with the intention of providing as much information thought to be required to follow the instructions effectively. Drawing from the principles of PROM development, all instructions were written in plain language without technical terminology, with the intention that they could be easily understood by patients [46,85].

Expert members of the study team were consulted to help draft the preliminary version of the photography instructions. This was to confirm that they met clinical and practical requirements for photographing wounds. Experts included two consultant surgeons (J.R, J.M.B) and a medical photographer (A.S.). Comments and suggestions were iteratively incorporated to revise the earlier versions of the instructions before they were pre-tested with study participants (described in more detail later in this chapter; section 4.6.3).

Component 2: process for transmitting images

The second key component of the method for obtaining patient-generated wound images remotely was for patients to be able to digitally transmit the images that had been taken. The second objective of the study was, therefore, to adapt existing IT software with the appropriate facility to enable patients to transmit wound images to a healthcare team or research group. The use of existing software without the need to develop an app or new electronic platform was important in this study, to minimise complexity, costs and resource use and maximise the potential use of the method in future research and clinical settings.

An important feature of the IT software for patients to transmit images was considered to be its suitability and compatibility for use with a mobile device. This is because it was intended that participants would use their smartphones or tablet computer to take the image of their wound, where possible. Requirements of the IT software, therefore, were: i) a facility to upload

images, ii) a suitable interface to use with a mobile device and iii) safe and secure transmission of data.

Suitable software for collecting electronic data from study participants known to the author of this thesis was utilised for this study. Developed specifically for research studies, REDCap (Research Electronic Data Capture) software is a secure web application for building and managing online surveys [123]. The software has the facility to collect most types of data, including digital images. REDCap software is well established and tested. As of March 2020, it has been used in nearly 4000 institutions in 136 countries, 857,000 projects and by over 1.2 million users [124]. REDCap was therefore chosen as the software to use in the current study because it addressed all the requirements for patients to upload and transmit images remotely for the current study, including an interface that is suitable for use with a mobile device (Box 9).

Box 9. Functionality of REDCap software relevant to the requirements for obtaining images from patients remotely

i) secure data transfer, addressing privacy and patient safety concerns
ii) easy to use and manage data
iii) low cost for implementation and supported by the University of Bristol
iv) easy to access from anywhere with a secure web connection
v) customisable survey / data collection forms including the facility to collect images
vi) advanced features including automated reminders
vii) regulatory compliant

Designing the process for transmitting images: an online survey for participants

The process for participants to transmit images of their wounds was designed as an online survey that included the facility to upload images. The survey was designed using the survey developer built into the REDCap software, in conjunction with an expert REDCap administrator employed by the University of Bristol (A.H.).

The online survey and steps for uploading the images were tested by the author of this thesis and other members of the study team during the survey development. This was to ensure that the steps to upload images worked as intended and was appropriate for different devices before the next phase of the study and pre-testing with participants.

4.6.3. Assessing acceptability: pre-testing the photography instructions and process for transmitting images

After the two components of the method to obtain images from patients – that is, the preliminary version of the photography instructions and the process for transmitting images - were developed, they were pre-tested with a sample of potential users. Drawing from the principles for PROM development, the aim of pre-testing the photography instructions was to ensure that they were acceptable, comprehensible and comprehensive to effectively take an image of the wound [46]. Further aims were to explore the acceptability of the language, format and length of the photography instructions, and obtain general feedback and suggestions so that necessary revisions could be made for their improvement. Similarly, the aim for pre-testing the process for transmitting images was to ensure that it was acceptable to patients and functioned as intended [125,126].

Drawing further parallels with the methods used for PROM development, pre-testing was undertaken through one-to-one cognitive interviews with participants [46]. Interviews also included observation of participant whilst following the instructions to take wound images and whilst completing the process to transmit the images. Observation-based methods are recommended for pre-testing respondent's responses to completing data collection instruments to identify where a problem may occur in carrying out any steps [127]. They were, therefore, considered appropriate for being able to identify any potential issues or problems patients had understanding the

photography instructions . The methods were also appropriate for the human-system interaction aspect of the procedure and the requirement for patients to use a digital device to take and transmit the images. The observation allowed for the author of this thesis to see how participants carried out the task of taking an image of their wound using their own mobile devices and any problems that were encountered, serving as a further test of acceptability. Potential barriers to taking and transmitting images could also be effectively explored and addressed, where possible, to ensure they could be addressed before further testing of the method with a larger sample of participants.

a) Participants and recruitment

The study to pre-test the method was named "The Selfi wound study: self-taken images of surgical wounds (Phase A)". Ethics approval was granted by the UK Health Departments Research Ethics Service NHS REC West Midlands - Coventry and Warwickshire Research Ethics Committee (18/WM/0096).

Sampling

Potential participants to pre-test the method for taking and transmitting wound images were sampled to be representative of the target population intended for SSI assessment after leaving hospital. These were patients who had recently undergone general abdominal surgery or vascular surgery. These specialties were selected because they have a relatively high rate of surgical site infection [17,128] and it was of interest to explore the potential

use of this method for remote SSI assessment in these patient groups. Participants were purposively sampled to ensure diversity across a range of demographic and surgical characteristics including age, site of surgical wound, size of surgical wound and characteristics of wound healing problems. This sampling technique was selected to address representativeness of the sample as much as possible.

Inclusion criteria were:

1. Patients with a closed primary surgical wound
2. Aged 18 or over
3. Ownership or access to a smartphone or digital camera
4. Ability to receive and access emails in their home setting
5. Willingness to remove wound dressing if appropriate and/or see their own wound
6. Willingness to undergo a face-to-face cognitive interview

Exclusion criteria were:

1. Prisoners
2. Adults lacking capacity to consent
3. Lack of ability to read/understand English that would preclude successful following of the photography instructions or process to transmit images

4. Patients with a complex open wound or a wound healing by secondary intention
5. Patients with a wound on part of their body that would make them identifiable from a photograph.

No pre-determined sample size was defined based on recommendations that saturation of data (that is, when all data are grouped into categories and no new categories are identified) in cognitive interviewing is considered to be more important than the number of patients interviewed, drawing from the approach for pre-testing PROMs [129].

Identification of potential participants

Potential participants were identified from pre- and post-surgical clinics and wards within two NHS hospital trusts (University Hospitals Bristol NHS Foundation Trust and North Bristol Hospital NHS Trust). Identification of potential patient participants was performed by research nurses within these hospitals, identified from clinic and ward lists and staff's knowledge of patients on the ward.

Recruitment and consent

Potential participants were approached in person by research nurses at the participating hospital trusts. A verbal explanation of the study and a paper-copy information leaflet were provided (Appendix 28). This leaflet included detailed information about the study to ensure the potential participant had sufficient knowledge about the study aim, what they would be asked to do

and how their data would be used. Those who expressed an interest in taking part were asked to provide their contact details. These were documented by the research nurse on a study-specific data collection form. Contact details were passed on to the author of this thesis at the University of Bristol, including expected or actual date of discharge from hospital and the patient's preference on when was best to contact them (day/time). Demographic and clinical data (including age, sex, date of surgery, type of surgery and location of wounds) was also included to inform the purposive sampling strategy (described above).

After discharge from hospital, potential participants were contacted by the author of this thesis by telephone or email. A further opportunity to ask questions about the study was provided. A visit to conduct a cognitive interview with observation was arranged for those continuing to be interested in taking part in the study. Visits were scheduled to occur within approximately 30 days (the recognised timeframe within which an SSI typically occurs [32] and, therefore, appropriate for when the method would be intended to be used in practice) after having surgery at a convenient day and time to the participant. Written informed consent was taken at the time of the visit (Appendix 29).

b) Procedure for participants: cognitive interview with observation

Cognitive interviews with observations were conducted face-to-face by the author of this thesis who is trained in qualitative research methods. These were single (one-off) interviews with observations, conducted with each participant in their preferred setting (home or other suggested location).

Taking the wound images

Participants were provided with a paper-copy of the photography instructions for taking a standardised image of their wound using their own smartphone or mobile device. Participants were asked to read through and follow the instructions to take the photograph as independently as possible. The use of a prop (e.g. a selfie-stick or mirror), if helpful, was available at the choice of the participant. To protect the participant's privacy and dignity, the author of this thesis offered to step out of the room or told the participant that they were free to go into another room to take the wound photograph, as preferred. Whilst reading the photography instructions and taking wound images, participants were asked to 'think aloud' [101,127]. This involved verbalisation and articulation of thoughts as participants read and carry out the instructions. This served as a test of comprehensibility, to examine how the instructions were being interpreted and check they were being understood as intended [127].

Transmitting the wound images

During the visit, the author of this thesis used a laptop to access the study database (designed with REDCap software) and added the participant as a new participant on the database, along with their email address. This triggered an invitation email to be sent immediately to the participant including a hyperlink to access the online survey to enable them to transmit their wound images. Participants were then asked by the author to access their emails and click on the hyperlink to log in to the survey. The survey included a step-by-step process with written instructions on how to upload and transmit their wound image(s). The participant performed this task in the presence of the author, so that an observation of the process could be carried out and any problems identified.

The author of this thesis took a non-participatory role and intervened as little as possible during the process of taking and submitting the wound images, unless the participant requested help or was visibly having problems with completing any of the steps.

c) Data collection

Basic demographic and clinical information were collected during the visit, to allow for a descriptive analysis of the study sample. Level of familiarity and experience with using mobile devices with digital camera facilities was also collected using a researcher-completed study-specific data collection form. Items were based on examples from a similar study in this field [81]. These data were collected in order to examine the demographics of the sample and

ensure the sample was as broad as possible to be representative of the target population expected to undergo remote wound assessment.

Cognitive interviews were audio-recorded with participants' permission, using a hand-held audio-digital recorder to record verbal data for the author to refer to during subsequent analysis. To collect non-verbal data during observations, the author took written field notes [127], including documentation of any requirements for help from a third party (e.g. family member or author of this thesis) or the use of any props and whether any issues, problems or confusion were encountered when taking and transmitting images [101].

After taking and transmitting the images, the author of this thesis discussed the process with the participant and followed-up on any observations or issues encountered, using probing questions aimed to explore problems or confusion further [101]. A pre-written prompt sheet was used to guide this process (Appendix 30). The prompt sheet was adapted throughout the course of the pre-testing phase of the study based on emerging findings, including new areas of focus derived from earlier interviews/observations. A set of pre-defined, targeted 'debriefing' questions aimed to elicit further experiences and opinions on any aspects of the photography instructions or performing the tasks of taking and transmitting the images were included [127].

d) Analysis

Audio-recordings of cognitive interviews were replayed and summarised in written memoranda (memos). This included bullet points of observations and any issues directly relevant to taking the photograph or transmitting the images. Key points and any other relevant feedback for improving the photography instructions or the process for transmitting images were summarised at the end of the memo. Field notes were incorporated into memos to add further details where relevant [101].

The photography instructions, written text within the online survey and the steps to transmit the images were revised as findings from the interviews emerged and analyses progressed. Urgent changes (e.g. changes that were crucial to be able to perform the tasks appropriately, such as necessary technical edits to the online survey) were made immediately before the following interview/observation with the next participant. Non-urgent changes (for example, suggested alternative wording) were made after a block of several interviews/observations to enable further exploration and understanding of the potential problem. Changes and revised versions of the photography instructions and system were tested with subsequent participants as an iterative process throughout the pre-testing phase [101].

All changes were documented in an Excel file as an audit trail, with detail of the reason for the changes and participant interviews providing supporting evidence for the reason for the change. Interviews/observations and analyses continued until saturation, that is, until there was no further substantial evidence from interviews/observations that further changes were required to improve the photography instructions and process to transmit the images [91].

4.7. Phase 2 – Evaluation

4.7.1. Objectives for Phase 2

The objectives for this phase of the study were:

- to examine the feasibility, usability and acceptability of the method taking and transmitting images with a large sample of patients after having surgery, including an examination of image quality.

Phase 2 of the study focused on evaluating the method for obtaining patient-generated wound images. This phase of the study was conducted to assess the potential use of the method for future widespread use in research or routine clinical practice. The evaluation phase involved testing of the method remotely with a large sample of patients who had recently undergone surgery. A new and larger sample of participants to those that were involved in the development phase were required, to collect data to test the method on a wider scale [46]. The methodological approach for evaluation of the method drew on the principles for field-testing a new PROM, including a need to test feasibility and acceptability of the method on a wider scale. The methodological approach also drew on principles relevant to the evaluation of electronic data collection systems and human-system interaction with digital technology, that is, a need to test usability. For the purpose of this study, usability was considered at a generic level, that is, the broad usability of the method for patients to take and transmit images using their own digital devices (rather than the specific usability, for example, of a particular make or model of smartphone). This was because the aim of the study was to evaluate

the overall method, with a pragmatic view that future use of the method in practice, patients would have access to a wide variety of types of devices to take and transmit images.

4.7.2. Principles for evaluating human-system interaction

The method to obtain patient-generated images required patients to first take a digital image of their wound and then transmit the image electronically. Both these tasks required the use of digital devices and technology. The evaluation of a process that involves an interaction between humans and digital technology and/or electronic systems lends itself to a contemporary methodological approach; one that focuses on evaluating 'usability' of that technology/system. This approach draws on the principles specified by the International Organization for Standardization (ISO), an international standard for evaluating "human-system" interaction and the usability of digital systems [130,131]. The ISO approach is recognised as an emerging approach in the field of healthcare where there is a lack of scientific methods for evaluating electronic systems and mobile healthcare (mHealth). The ISO approach been adopted as an established method for evaluating electronic devices or systems intended for patient use. For example, NHS Digital, the national information and technology partner to the health and social care system, endorses the ISO requirements and recommendations for evaluating new digital tools [132]. The ISO approach and similar tests of usability have also been adopted in research studies worldwide to evaluate electronic systems for collecting PROMs and other data from patients, some of which

have included images [83,126,133-136]. A study by Gunter et al. in the US, for example, used the ISO standard to guide the usability testing of a new smartphone app for surgical wound monitoring after hospital discharge [83].

The ISO definition of usability is "*the extent to which a system, product or service can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use*"[131]. The ISO approach allows for an evaluation of how well a patient can perform the task of taking and transmitting digital images of their wounds, and whether the images are sufficient quality for remote SSI assessment. The ISO usability-testing approach was, therefore, chosen as a suitable methodological approach to include in the evaluation phase of the current study. More detail on the ISO definition of usability, specifically the components of effectiveness and efficiency, and how they measured in the current study are described later in this chapter (Section 4.7.7). Whilst it is recognised that satisfaction is also included as a component of the ISO definition of usability, satisfaction is further defined by ISO as the "*extent to which the user experience that results from actual use meets the users' needs and expectations*"[130]. Assessment of satisfaction was considered to apply to a later, full stage of evaluation beyond the scope of this PhD research, when the method would be implemented in a research or clinical setting and the images used to make an assessment of the wound for SSI in practice. The current study focused on an initial evaluation of the method, with respect to its intended use to assess wounds for SSI in future applications of the method. An assessment of the whether the method met the users' needs and expectations for SSI assessment, therefore, was not considered within the scope of this study.

Specific objectives of the evaluation phase of the study and the key properties being addressed were:

1. to evaluate **feasibility:** examine the number of participants approached and recruited, including reasons for declining or withdrawing from the study
2. to evaluate **usability:**

   i) effectiveness: examine the proportion of participants successfully taking and transmitting wound images

   ii) efficiency: examine the time taken for participants to respond to the request to transmit images, and the need for any reminders. Examine participant's reports of the time taken to take the wound photograph and whether any help was needed to take or transmit images.
3. to evaluate **acceptability**: examine participant feedback and experiences to understand reasons for not taking or transmitting wound images, and problems that occurred or any issues encountered.
4. to evaluate **quality of the wound image(s).**

4.7.3. Participants and recruitment

The evaluation of the method was the second phase of the "The Selfi wound study: self-taken images of surgical wounds". Ethics approval was granted by the West Midlands - Coventry and Warwickshire Research Ethics Committee (18/WM/0096) in a single application with the development phase of the study, as described earlier.

Sampling

Similar to the pre-testing phase of the study, patients undergoing general abdominal or vascular surgery were sampled to test the method remotely. As previously described, these specialities were chosen because they have a relatively high rate of surgical site infection and therefore applicable for potential use of the method in future applications. Criteria for eligible participants were identical to those described for Phase 1 participants (section 4.6.3), excluding the criterion "willingness to undergo a face-to-face cognitive interview". Face-to-face interviews were not relevant to this phase of the study because evaluation focused on testing the method remotely. Potential participants were purposively sampled to be representative of a widespread target population potentially relevent for remote wound assessment in research studies or clinical practice. Diversity across a range of participant demographic and surgical characteristics was, therefore, required to evaluate the method in as broad a sample as possible.

Identification of potential participants

Research nurses and surgeons at the two recruiting hospital trusts (described in section 4.6.3) identified potential participants from pre- and post-surgical assessment clinics and ward lists. Research teams were asked to use a study-specific screening log to record the number of patients approached for recruitment to assist with analysis of feasibility (described in detail below).

Recruitment and consent

Potential participants were approached in person by research nurses and surgeons, in a similar way to Phase 1 (section 4.6.3). A verbal explanation of

the study and a participant information leaflet specific to this phase of the study were provided (Appendix 31). Potential participants were given as long as they required to consider the study before being re-approached to ask if they were interested in taking part. Opportunities to ask questions prior to making any decision on whether to participate were provided. Recruitment to the study was performed by the study nurses before the participant was discharged from hospital. Written informed consent was taken by the research nurse or surgeon at the time of recruitment.

4.7.4. Procedure for participants: remote testing

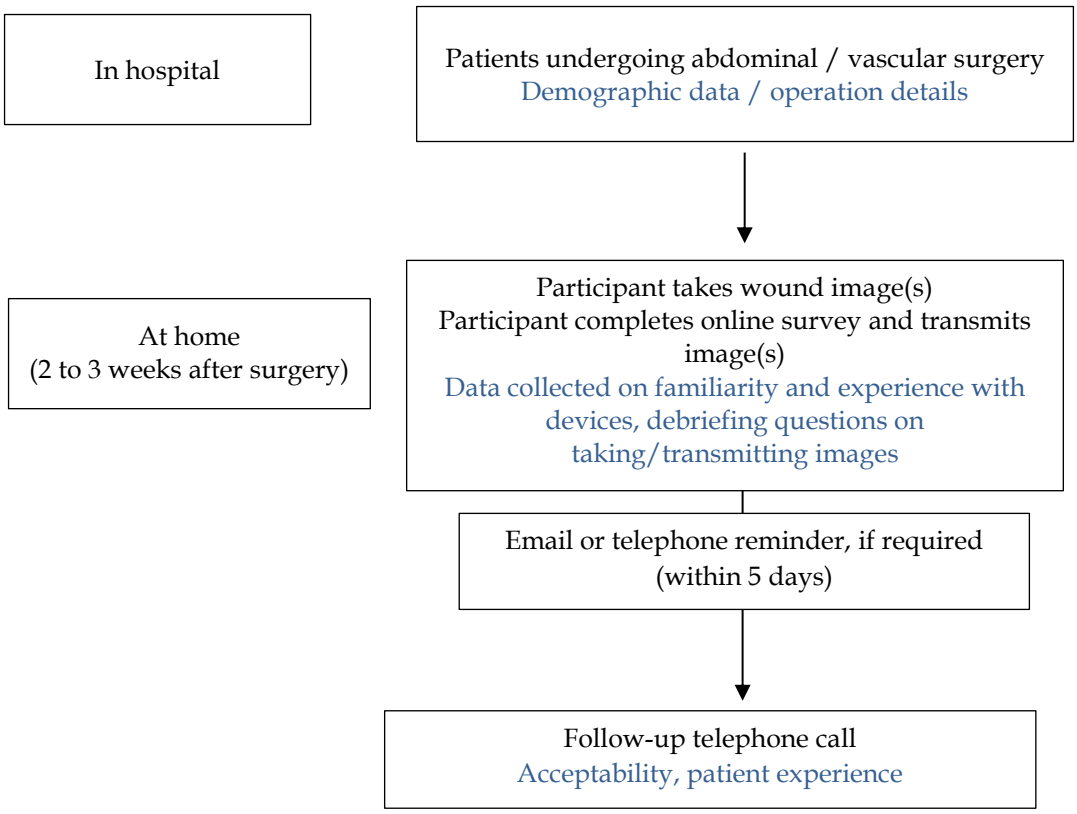
Approximately two to three weeks after the date of surgery (or later, if the participant had a prolonged stay in hospital), written study information and a paper copy of the photography instructions developed and pre-tested in Phase 1 were sent to the participant's address via post. The two- to three-week timeframe was chosen as it was relevant to the recognised timeframe for SSI assessment (up to 30 days) [32], and was, therefore, appropriate for future implementation of the method in research studies of routine practice. A paper copy of the photography instructions was provided rather than an electronic version based on participant preference determined in Phase 1 interviews. Preference to have a paper copy of the instructions that could be referred to whilst taking the photograph was reported. The written study information conveyed to the participant that they would receive an email to tell them how to transmit the image electronically. The email was automatically generated by the study REDCap database designed in Phase 1, co-ordinated by the author of this thesis to coincide with the participant receiving the photography instructions by post (that is, on the same or following day). The

email provided the participant with a hyperlink that led them directly to the online survey. As described in Phase 1 (section 4.6), the hyperlink was unique for each participant to enable any data entered by the participant to be securely recorded within that unique record. The survey included a step-by-step process, developed and pre-tested in Phase 1 (section 4.6), for participants to upload their wound image(s) from the image library on their mobile device. After the step to upload the image(s), the survey included further items to assess participants' familiarity and experience with technology, a set of 'debriefing' questions (Appendix 33) and the 18-item SSI outcome measure (described in Chapter 2 and 3). Reasons for including the debriefing questions and outcome measure are described in detail below.

4.7.5. Data collection

A schematic overview of the data collection for this phase of the study is shown in Figure 4-3. A detailed description of data collection follows in subsequent paragraphs under the subheadings pertaining to the properties being evaluated.

Figure 4-3. Data collection for evaluation of the method for obtaining patient-generated wound images



i) Participant characteristics

Demographics and operative data

Participant demographic details were collected by the research nurse or surgeon at the time of recruitment. This included sex, age and whether they would be alone or with others immediately after leaving hospital following surgery (collected with relevance to evaluating whether help might be available for participants to take and transmit images, if required). Basic operative details were recorded including the type of surgery, urgency of surgery (that is, whether surgery was elective or unplanned), modality of surgery (for example, open or keyhole surgery) and location and number of wounds. Data were collected on a recruitment case report form using closed questions and primarily with multiple choice responses for ease of analysis. Collection of these data were in order to facilitate purposive sampling to ensure a representative sample as recruitment proceeded, and to potentially explore any characteristics that might explain particular problems or issues during analysis. Data were subsequently passed to the author of this thesis and entered on to the study database.

Familiarity and experience with devices

Data on familiarity and experience with devices were collected directly from the participant using closed questions and multiple choice as part of the online survey (described below). These data were collected to be able to describe the competency of the study participants in order to facilitate interpretation of the findings.

Wound healing

The online survey also included the 18-item SSI outcome measure developed as part of this PhD thesis (Chapters 2 and 3; Table 3-26). The purpose of collecting the SSI data was to explore electronic adaptation of the outcome measure for digital use. This was considered to be valuable to explore for further validation of the outcome measure as an electronic PROM following this PhD thesis. It was not intended to include these data in the current study analysis.

Descriptive statistics (mean, median and inter-quartile ranges (IQR) for continuous data and numbers and percentages for categorical data) were used to summarise participants' demographics, operative data and experience/familiarity with devices. Analysis were performed using STATA software version 14.0 [106].

4.7.6. Assessing feasibility: participant eligibility and recruitment

An evaluation of feasibility was important to examine whether a method for taking and transmitting wound images was practical and possible for patients in the target population to be able to do it [46,125]. Feasibility was explored by examining the potential number of participants that might use the method if it were to be implemented in research or routine practice to assess wounds for SSI remotely. Specifically, this was examined by looking at screening and recruitment data and the number of participants that consented or declined to take part in the study.

Screening and recruitment data

Recruiting teams were asked to record data on patients that were approached to take part in the study. A study screening log was provided for centres to record anonymised patient details including date of birth, sex and surgical procedure. Any reasons for ineligibility or declining participation in the study were also recorded. This data was collected to assess the number of participants who were eligible for the study, for example, to identify the number of participants who owned or had access to a mobile device with a camera.

Specific screening and recruitment data examined were:

i) the number of participants eligible;

ii) the number of participants approached and recruited;

iii) reasons for declining the study.

All data to examine feasibility were analysed descriptively using summary statistics.

4.7.7. Assessing usability: effectiveness and efficiency

An evaluation of usability was considered to be important for this study phase, to assess whether images could be obtained from patients using their digital devices without problems and in a timely way without too much burden or need for extra resources [131]. These properties are important consideration for future implementation of the method in research studies or routine practice.

i) Effectiveness

The ISO definition of usability includes effectiveness, defined as "*accuracy and completeness with which users achieve specific goals*"[131]. In line with examples from other studies testing usability of electronic systems to collect PROM data and mobile phone apps, the ISO definition of effectiveness was interpreted as the ability of the users to complete pre-determined tasks [83,126,133]. With relevance to the current study, this can translate to how accurately and completely patients were able to take and transmit an image of their wound. The effectiveness of the system to collect participant-generated images was, therefore, evaluated by examining the number of participants who were able to i) successfully take an image of their wound and ii) successfully transmit their images. Specifically, number of online surveys that included a submitted image and further information collected via follow-up telephone calls with participants were examined.

Descriptive statistics were used to describe the demographic and operative details of participants that successfully took and transmitted an image and those that did not complete the tasks (that is, did not complete step 1: taking the image or step 2: transmitting the image). Chi-squared tests for categorical data were used to compare demographic and operative details for these two groups [112]. Analyses were performed using STATA software version 14.0 [106].

ii) Efficiency

The ISO definition of usability also includes efficiency, defined as "*resources used in relation to the results achieved*", with typical resources including time, human effort, costs and materials [131]. In other similar studies this had been considered as the level of resource required to perform the task [126]. In line with these examples, the current study examined the efficiency of the method to obtain wound images from participants in four ways:

a) the time taken to obtain images from participants;

b) the need for reminders;

c) time taken for participants to take the wound image;

d) whether help from others was required for participants to take and/or transmit images.

a) Time taken to obtain images from participants

The time taken to obtain images from participants was calculated as the number of days it took for participants to respond to the invitation email and

transmit their wound images. The REDCap software automatically recorded the date that the invitation email was sent to participants asking them to log in to the online survey and transmit their images. The date that participants submitted the survey data was also automatically recorded. These data were used to record the number of days for the participant to respond.

b) The need for reminders

The author of this thesis monitored the REDCap database regularly to identify new data (that is, survey responses and successfully transmitted wound images) that had been received from study participants. Participants for whom no data had been received within five days were sent a reminder. The reminder was either: i) a standardised email generated from the REDCap database, including the hyperlink to the individualised record, or; ii) a telephone call from the author of this thesis, depending on participant's preference for the type of reminder asked at the time of recruitment, as an attempt to maximise responses.

c) Time taken to take the wound image

Participants reported how long it took to take the wound image(s) as part of the online survey. This was assessed with a single 'debriefing' item with a four-level categorical response option ("less than 5 minutes", "5 to 10 minutes", "10 to 15 minutes" or "more than 15 minutes").

d) Help from others to take/transmit images

Two debriefing questions were included in the online survey to examine whether help from another person was needed to take or transmit images. The first question asked whether the participant had taken the wound image themselves or if someone else had taken it for them. The second question asked whether help was needed to upload the image. These were closed questions with yes/no response options.

4.7.8. Assessing acceptability: participant feedback and experiences

Acceptability of the method for participants to take and transmit images was considered an important property to address when testing the method remotely. This was in order to assess its appropriateness and ensure that patients would be willing to use the method in future implementation of its use [46]. Two approaches were taken to explore acceptability of the photography instructions and process to transmit images, through the collection of feedback from participants and understanding their experiences. Methods included:

a) Free text space (optional completion) as part of the online survey. The aim was to provide an opportunity for participants to include any further information or any feedback about taking or transmitting their images.

b) Follow-up telephone calls to elicit participants' views and feedback. A sub-sample of the study population were contacted to further explore

participants' experiences (Figure 4-3). Participants were selected for a follow-up call if there was an indication of a problem in their response to the debriefing questions (for example, if participants had reported that help was needed), or were selected to be contacted for general feedback, at the choice of the author of this thesis. Follow-up calls were semi-structured, exploring participants' experiences, views and opinions of taking and transmitting their wound images, facilitated by a prompt sheet (Appendix 34). The purpose of this follow-up call was to elicit feedback about taking and transmitting images to identify any critical changes that may be required to consider for future use of the method.

The author of this thesis documented the date of telephone calls and made handwritten notes of key issues whilst talking to participants. Reasons participants gave for not taking and/or transmitting images were documented verbatim, if applicable. These were subsequently entered in an electronic spreadsheet (Excel).

4.7.9. Assessing image quality

As a final step of the evaluation of the method within the scope of this PhD, the quality of the images was assessed. A judgement of whether the images were considered to be of suitable quality to potentially assess the wound for SSI was sought from three independent clinical assessors. It was not the intention that the images were used to actually assess the wound for SSI in the current study. The intention was to demonstrate whether the method was

effective in providing an image that would be fit for purpose to assess a wound for SSI, with respect to the intended clinical use in future applications of the method.

Assessors were academic clinical lecturers from the Bristol Centre for Surgical Research, including two general surgeons (S.P. and N.B.) and one vascular surgeon (M.Q.). Assessors were selected because they were experienced in post-surgical follow-up and conducting assessments of the wound for SSI in clinical practice. It was considered, therefore, that these individuals would be appropriate for judging the suitability of the wound for remote assessment. Three assessors were selected to ensure methodological rigour and to allow for an examination of the consistency in the assessments across the different individuals [107]. The assessors independently (that is, individually and without the knowledge of the other assessors' judgements) viewed each wound image on a desktop computer screen. Images could be magnified using the zoom function if required. The author of this thesis sat with the assessor as they viewed each image. The assessor was instructed by the author of this thesis to look at the image and judge the quality by answering the following question: "Is the image sufficient to appropriately assess the wound for surgical site infection?". Verbal responses of 'Yes' or 'No' were requested and recorded by the author of this thesis. When the response was 'No', further explanation of the reason was sought and documented in written notes. Reasons were categorised by the author of this thesis as being i) reasons that could be resolved with modification to the photography instructions and ii) reasons that could not be resolved with modification to the photography instructions. This distinction was made to distinguish

between reasons that could be addressed in future revisions of the photography instructions, if needed, and reasons that could not be addressed by revisions to the method and that instead required a face-to-face assessment of the wound.

An analysis of inter-rater agreement on judgement of the quality of the wound images was performed to examine consistency in the judgements across assessors [107]. Several statistical approaches are available to examine inter-rater agreement when there are three or more assessors, as in the case of the current study. Choice of which approach to use depends on various factors and assumptions. Where no missing ratings exist for any of the assessors and ratings are nominal (that is, categories without values such as 'yes' and 'no'), as is the case for the current data, calculating a percentage agreement and Krippendorff's alpha coefficient is recommended [107]. Values between 0.4 and 0.75 are considered to indicate intermediate to good agreement (based on Fleiss' kappa benchmark scale) [107]. A sensitivity analysis excluding images that were judged as insufficient for reasons that could not be improved with modifications to the photograph instructions. This was to examine whether the level of inter-rater agreement was improved when wounds that could not be sufficiently assessed without a face-to-face appointment were excluded from the analysis.

4.8. Summary

This chapter has described the aims, objectives, methodological approach and study design for the development and evaluation of a method to obtain patient-generated images of surgical wounds for SSI assessment after hospital discharge. It describes the rationale for combining two methodological approaches to develop and evaluate the method, drawing on principles from both PROM development and evaluations of human-system interaction. The essential properties required of the method to take and transmit images, and how they were addressed, are described, including content validity, feasibility, usability, acceptability and image quality. Patient and public involvement, and the importance of seeking advice and opinions to inform the study design and conduct are described.

The chapter describes the study methods in two phases. In the first phase, the methods for developing photography instructions for patients to take a standardised image of their wound using own mobile devices are detailed. This includes a content analysis of existing literature on how to photograph wounds for use in clinical practice or research. The rationale for adapting an existing IT software system to develop a process for patients to transmit the images through an online survey is described. In the final part of the first study phase, methods to pre-test the photography instructions and process of transmitting images with patients are described. This included one-to-one cognitive interviews with observation of patients testing the method in the presence of the researcher. Next, the chapter described the methods applied in second phase of the study, to evaluate the method for patients to take and transmit images of their wound. This involved testing the method remotely

with a large sample of patients after leaving hospital following surgery. Methods for recruitment, data collection and analysis are described. The findings from this study will now be reported in full in the following chapter.

CHAPTER 5. RESULTS: STUDY 2

DEVELOPMENT AND EVALUATION OF A METHOD FOR REMOTE WOUND ASSESSMENT USING PATIENT-GENERATED DIGITAL IMAGES

5.1. Introduction

This chapter reports the findings from the development and evaluation of a method for patients to take and transmit images of wounds after leaving hospital, for potential use for remote SSI assessment. The chapter is structured to mirror the methods chapter and concludes with a brief discussion, including of the strengths and limitations of the study.

The study was designed in two phases: 1) development and pre-testing of the method, and; 2) evaluation of the method. An overview of the study is provided as a reminder in Table 5-1, including the methods applied and the number of participants recruited to each study phase.

Table 5-1. Overview of the study phases, methods applied and number of participants, where applicable

Study phase	Methods applied	Number of participants
Phase 1 – Development and pre-testing	Content analysis of existing wound photography literature	n/a
	Operationalisation of key features for taking wound images to draft photography instructions for patients	n/a
	Adaptation of existing IT software for transmitting images	n/a
	Pre-testing using cognitive interviews with observation	16
Phase 2 – Evaluation	Testing the method remotely with patients after surgery Follow-up telephone calls Assessment of image quality	91

5.2. Patient and Public Involvement

Advice and feedback from PPI consultations and the public engagement event were used to inform the study name and the PIL for optimising recruitment and participation. PPI contributors' preferred study acronym was selected. Specific advice on content to include in the PIL included how to describe technical words such as 'database' and 'upload', to specify the timing of when participants would be expected to take a photograph, and to describe how the images would be used. Members of the PPI group also emphasised the importance of reassuring participants about the handling and storage of their wound images to maintain confidentiality. Further suggestions from PPI members on the study design were provided. Specifically, these were recommendations to collect data on the type of mobile device patients used to take images and to explore whether participants would have access to the right software to transmit images to allow a broader examination of feasibility of the method for future application of its use in the general population. A potential issue that some patients and/or their carers might not want to look at the wound was raised. This led to the inclusion of this topic in the prompt sheet for topic to discuss in the cognitive interview study to pre-test the method. In general, there was positive support for the study idea from PPI contributors and the members of the public that were consulted, with a view that anything that would help monitor the wound post-discharge was encouraged.

5.3. Phase 1 – Development and pre-testing

Phase 1 of the study focused on developing the two components of the method required to obtain patient-generated images: i) photography instructions for patients and ii) a process for patients to transmit images.

5.3.1. Assessing content validity

Component 1: development of photography instructions for patients

i) Content analysis of existing literature

Source documents

A total of 11 documents providing guidance on photographing surgical wounds for use in clinical practice or research were identified through expert-knowledge and the scoping search. Documents included published guidelines for professional medical illustrators (n=1) [77] , published papers on wound photography or studies that evaluated wound photography (n=7) [59,121,137-141] and unpublished photography protocols from research studies (n=3) [142-144].

Identified key features for photographing wounds

Data relevant to taking standardised images of the wound were extracted from the source documents and grouped into categories based on the feature of photography they related to. A total of 21 key features were identified from at least one of the source documents (Table 5-2).

Table 5-2. Key features to consider for photographing wounds identified from existing literature

	Key feature	Source document: Professional guidelines (n=1)	Source document: Published paper* (n=7)	Source document: Unpublished protocol* (n=3)	Example text (verbatim)	Feature included in preliminary version of photography instructions for patients
1	Protecting dignity	✓	✓	✓	"Extraneous clothing should be removed by the patient (or carers) but the patients' dignity should not be compromised."	✓
2	Preparation: wound cleaning	✓	✓	✓	"In general, wounds and the surrounding area (particularly the perineum) should be cleaned before photography; otherwise there may be confusion as to the condition and extent of the wound."	✓
3	Preparation: dressing removal	x	✓	✓	"If the patient has a dressing in situ, photographing the wound should coincide with planned dressing changes"	✓
4	Setting: where the image is taken	✓	✓	x	"Wherever possible, take the photo in a treatment room because the overhead lighting produces a better picture."	✓
5	Equipment: type of camera	✓	✓	✓	"Consideration must be made about whether photographs are taken on cameras or phones and whether the device used is owned by the clinician or the Trust"	✓
6	Lighting/Flash	✓	✓	✓	"A flash is used in all settings to ensure adequate and consistent lighting"	✓

Key feature		Source document: Professional guidelines (n=1)	Source document: Published paper* (n=7)	Source document: Unpublished protocol* (n=3)	Example text (verbatim)	Feature included in preliminary version of photography instructions for patients
7	Background	✓	✓	✓	"Backgrounds should be plain and unobtrusive providing no distraction from the area of interest"	✓
8	Position of participant	✓	✓	✓	"Comfortably positioned in the correct anatomical position"	✓
9	Scaling tool (i.e. ruler)	✓	✓	✓	"A scaling tool is advised as appropriate"	✓
10	How images are transmitted	✓	✓	✓	"Photos should be immediately uploaded, deleted from the camera and/or device and shared drive once this is completed"	x
11	Storage	✓	✓	✓	"Stored securely and disposed of securely when no longer required"	x
12	Patient identifier	x	✓	✓	"Before photos were taken, a 15-cm ruler with clear millimeter divisions was placed next to the wound as well as a patient identification number and the date of the assessment"	x
13	Distance from wound/framing	x	✓	✓	"The photograph is framed by altering the distance between the lens and the wound or using the zoom function if present"	✓
14	Angle/plane of camera to wound	✓	✓	✓	"The camera should be held perpendicular to the wound"	✓

	Key feature	Source document: Professional guidelines (n=1)	Source document: Published paper* (n=7)	Source document: Unpublished protocol* (n=3)	Example text (verbatim)	Feature included in preliminary version of photography instructions for patients
15	Focus	x	✓	✓	"Auto focus"	✓
16	Reviewing the image	x	✓	✓	"Review the picture on the back of the camera"	✓
17	Multiple images	x	✓	✓	"A second photograph of all wounds is obtained to ensure at least 1 good-quality photograph"	✓
18	Shadow	x	✓	x	"There should be no areas of shadow"	✓
19	Resolution	x	✓	x	"Good resolution (usable file size) and quality depends on the equipment used."	x
20	Colour control/calibration	✓	✓	✓	"Where colour is an important factor, it is useful (where practicable) to include a calibrated colour chart and/or grey card in the frame or at the beginning of a series of images."	x
21	Use of mirror as a prop	✓	x	x	"If a wound is located in an awkward position it may be helpful to use a large dental mirror"	✓

*feature mentioned in at least one publication

ii) Drafting the photography instructions

All 21 identified features from the content analysis of existing wound photography literature were considered for inclusion in the preliminary version of the photography instructions for patients. Five features were subsequently excluded as they were considered not relevant for inclusion in instructions for patients (Table 5-2). This was because they were not able to be controlled by the patient using their own mobile devices to take images (for example, resolution and colour calibration) or they related to later stages of the study (such as how images were transmitted and stored). Inclusion of a patient identifier number in the photograph was also excluded from the photography instructions as it was already determined for the specific study that images would be automatically stored within a unique participant record on a study database when the image was transmitted using the IT software (as described in the previous chapter). The remaining 16 features were formulated (operationalised) into items for a preliminary version of photography instructions for patients. One additional feature, handwashing, that was identified as important following review of the preliminary instructions by consultant surgeon was further included. Two symbols commonly used to illustrate the flash function and the reversed camera direction ("selfie mode") were included alongside item text with the aim of enhancing participant understanding for those less experienced with using cameras on their mobile devices.

Component 2: process for transmitting images

The online survey

The process for participants to transmit images of their wounds was designed as an online survey using REDCap software, as described in the Chapter 4. This included a facility that enabled participants to upload their wound images.

The stages of survey and process for transmitting images were designed as follows:

i) Invitation emails, including a hyperlink (underlined text for participants to click on) to log in to the survey, were generated automatically when a new study participant was added to the REDCap database by the author of this thesis. Hyperlinks were unique to each study participant and associated with an unidentifiable study ID.

ii) After logging in to the survey on their mobile device, participants were instructed to follow instructions guiding them through a step-by-step process to select and upload an image from their device's photo library. After uploading an image, instructions invited the participant to upload further images, by repeating the same steps, until all images were uploaded.

iii) The final stage of the survey asked participants to click on a 'submit' box, following which the data entered, including uploaded images, were transmitted and saved to the REDCap database.

iv) Researcher can then access the database to view and/or export data and images.

The survey was designed so that each step (for example, uploading of an image or survey item to collect information from participants) was suitable for different types of devices that participants potentially may use to complete the survey. For example, the survey was designed so that there was no requirement for participants to scroll down the screen on their mobile device regardless of whether it was a smart phone (with a smaller screen) or a tablet computer (with a bigger screen). This was considered necessary to make the process as simple as possible for any non-experienced users, following published recommendations to consider when designing electronic data capture systems for patients [125,145].

5.3.2. Assessing acceptability: pre-testing the components of the method

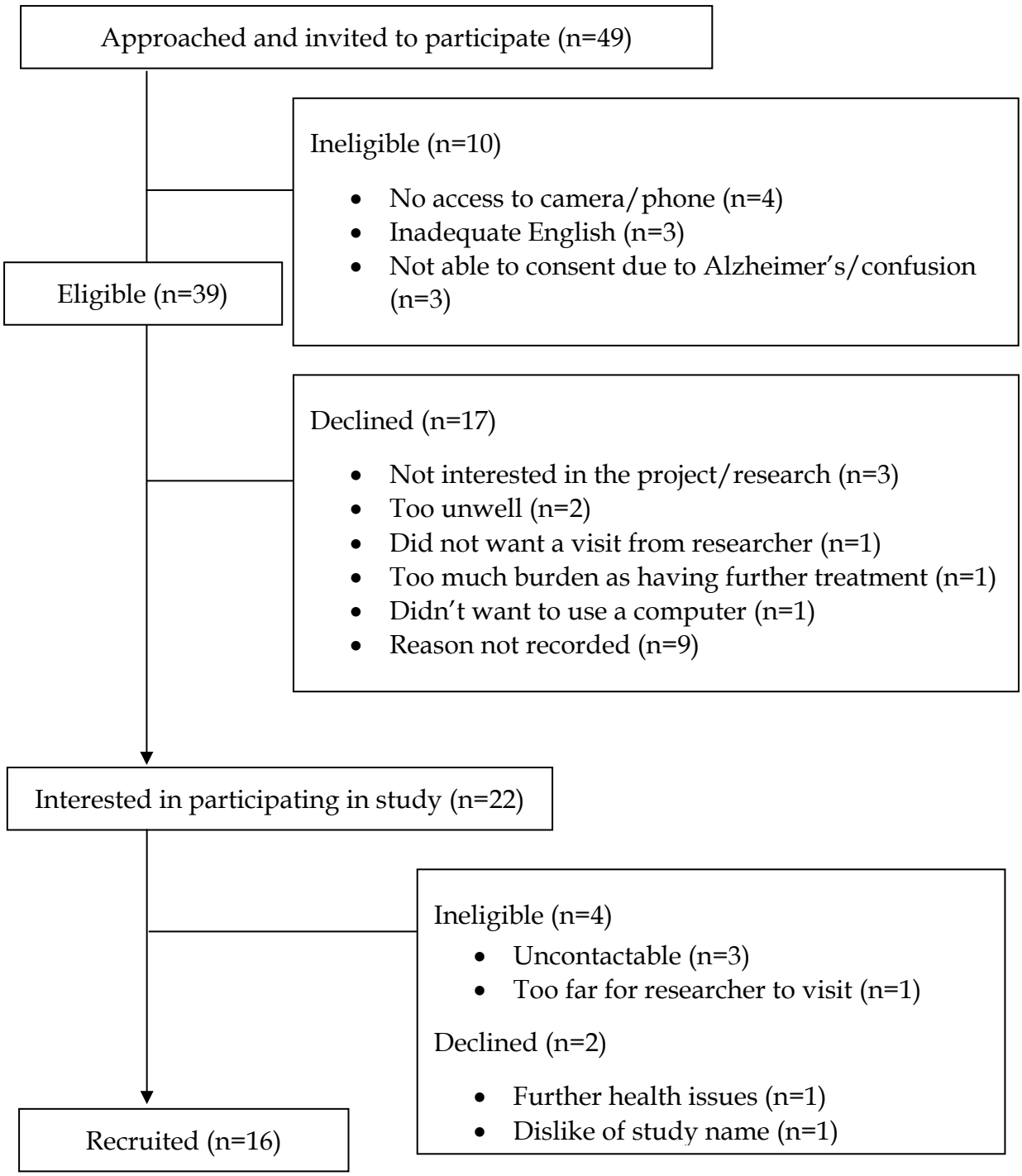
Methods to pre-test the photography instructions and process to transmit images included cognitive interviews with observation, with participants who had recently undergone surgery. The pre-testing phase of the study, "The Selfi wound study: self-taken images of surgical wounds (Phase A)" ran between June 2018 and November 2018.

i) Participants and recruitment

Data from the study screening logs from the two recruiting hospitals showed that a total of 49 patients were approached for participation. Of these, 10 were ineligible and 17 declined to take part. Reasons are provided in Figure 5-1.

Contact details for the 22 interested patients were passed on to the author of this thesis to telephone and discuss the study further. Of these, three could not be contacted, either because they were not available by telephone or did not respond to answerphone messages. One patient lived too far out of the feasible area for a home visit. Two patients declined participation in the study, one due to further health issues and one declining because they disliked the use of the term 'selfie' in the study name. The remaining 16 interested patients agreed to take part in the study and a time and place for a visit was arranged (Figure 5-1).

Figure 5-1. Recruitment flow diagram for the pre-testing phase of the study



Participant characteristics

Participant demographics, operative details and familiarity/experience with devices are shown in Table 5-3. The majority of participants were female (n=11, 68.8%) and had undergone lower abdominal surgery (n=9, 56.3%). Participants' ages were equally distributed across the age categories achieved by successful purposive sampling to invited participants across a broad spread of ages. The median time between patients' surgery and pre-testing the method was 28 days (range 12 to 69 days). The majority (n=13, 81.3%) of participants' wounds had healed by the time of the study visit. One participant had wounds that had mostly healed, although one wound still had steri-strip in place when they took their photograph. Two participants had wounds that had not yet healed and had dressings on at the time of the study visit. One of these participants was changing their own dressing at home and removed it voluntarily to take a photograph during the study visit. The other participant had arranged the study visit to coincide with a district nurse home visit and dressing change.

Experience with using devices ranged across the participant sample (Table 5-3). All but one participant described themselves as somewhat / moderately experienced or very experienced / expert with using a smartphone. The majority of participants were experienced in taking photographs with a smartphone or tablet, frequently taking photographs on a monthly (n=5), weekly (n=4) or daily (n=5) basis.

Table 5-3. Phase A participants: pre-testing (n=16)

Demographic/characteristic		n	%
Sex	Female	11	68.8
	Male	5	31.3
Age at time of interview (years)			
	21 to 30	2	12.5
	31 to 40	3	18.8
	41 to 50	3	18.8
	51 to 60	3	18.8
	61 to 70	2	12.5
	Over 70	3	18.8
Time since surgery (days)			
	<7	0	0.0
	7-14	1	6.3
	15-30	8	50.0
	>30	7	43.8
Type of surgery			
	Upper gastro/intestinal	6	37.5
	Lower gastro/intestinal	9	56.3
	Vascular	1	6.3
Experience with computers			
	Not experienced	2	12.5
	Somewhat/moderately experienced	6	37.5
	Very experienced/expert	7	43.8
	Missing	1	6.3
Experience with smartphones			
	Not experienced	1	6.3
	Somewhat/moderately experienced	8	50.0
	Very experienced/expert	6	37.5
	Missing	1	6.3
Experience with taking photos using smartphone/tablet			
	Not experienced	1	6.3
	Somewhat/moderately experienced	9	56.3
	Very experienced/expert	5	31.3
	Missing	1	6.3

Demographic/characteristic		n	%
Frequency taking photographs using smartphone/tablet			
	Never	0	0
	Yearly	0	0
	Monthly	5	31.3
	Weekly	4	25.0
	Everyday	5	31.3
	Missing	2	12.5
Type of device			
	Android	7	43.8
	iPhone	6	37.5
	Tablet	1	6.3
	Unsure	1	6.3
	Missing	1	6.3

ii) Findings from cognitive interviews with observation

Taking and transmitting the wound images

Several issues with taking and transmitting the wound images were identified during pre-testing. These are summarised below under three sections: i) relevance, comprehension and interpretation of the photography instructions; ii) feasibility/practical issues with photographing the wound, and; iii) technical issues with using the device to transmit images.

a) Relevance, comprehension and interpretation of the photography instructions

The overall aim of the photography instructions was to obtain a standardised image of the wound that would be suitable for remote assessment of the wound for SSI. During the iterative process of pre-testing and revisions, a number of issues with relevance, comprehension and interpretation of the instructions were identified. For example, an early version of the instructions asked participants to ensure that the flash on their camera was switched on. It was discovered during interviews that for some models of smartphone it was not possible to have a flash if using the front-facing camera, meaning that this instruction was not relevant for use with all devices. Another example was ambiguity over whether it was required to frame the whole wound in the photograph or whether it should be a close-up image with several taken if the wound was long. It was possible to overcome these issues with revisions to the instructions to improve clarity and precision. Revisions were then tested in subsequent interviews.

Participants provided suggestions to improve language and formatting for improved ease of use and comprehension. Specific examples included the use of the word "front-facing camera" and to streamline text to make the photography instructions as concise as possible.

b) Feasibility / practical issues with photographing the wound

It was possible for 13/16 (81.3%) participants to follow the photography instructions and take an image of their wound (Table 5-4). None of these 13 participants needed any help to take the photograph. Reasons that three of the participants were not able to take a photograph included: i) having a dressing in place (n=1; a community nurse expected to be present to remove the dressing, timed with the study visit, was delayed); ii) not knowing how to reverse the camera on the mobile device and did not seek help (n=1), and; iii) needing time to work out how to use the camera on the phone and did not want to try during the study visit (n=1). The practical issue of a dressing being in place was a potential barrier for participants to take images of wounds that had been previously considered by the study team.

Table 5-4. Summary of participants able to take and transmit images during pre-testing

	Number of participants (n=16)	
Component of method	**Able to complete component** n (%)	**Unable to complete component; reasons** n (%)
1. Taking an image	13 (81.3%)	3 (18.8%) • Low competence using camera on device (n=2) • Dressing in place (n=1)
2. Transmitting an image	12 (75.0%)	4 (25.0%) • No facility on device to connect to the internet (n=1) • Security warning (n=1) • Administrative; online survey not finalised (n=1) • Participant ended interview early (n=1)

c) Technical issues with using the device to take/transmit images

It was possible for 12/16 (75.0%) participants to transmit an image of their wound, taken either during the interview or using an existing photograph taken prior to the interview (Table 5-4). Two participants needed help from the author of this thesis to navigate through the steps to upload their images using earlier versions of the online survey, which were subsequently improved in later revisions. Reasons that the four participants were not able to upload an image were: administrative (the online survey was not finalised by time of the first participants interview; n=1), time (the interview was

finished early by the participant due to an expected appointment to attend hospital; n=1) and technical issues, including a security warning on a participant's device while attempting to access the internet (n=1) and no facility to access the internet on the device (n=1). This participant reported that they would have been able to use a family member's device to transmit their image if using the method in practice (that is, not a test setting).

Participant views on acceptability of taking and transmitting wound images

In general, the sample of participants that took part in the pre-testing phase of the study were supportive of providing images for remote wound assessment. There was no evidence to suggest any of the participants found the experience of seeing their wound upsetting, an issue considered as a potential barrier to the acceptability and, therefore, willingness to use the method in future. One participant described a family member and friend who had not wanted to look at their wound because they were squeamish. Conversely, there were many positive comments from participants about being able to take a photograph of their wound. One participant reported that they found viewing the image useful, because they could see their wound at closer proximity. Several participants reported that they had already taken images of their wounds prior to the invitation to take part in the current study. They reported that this was for their own interest, or so they could show others what the wound looked like. One participant had asked a nurse to take a photograph of their wound so they could see what the wound looked like immediately after surgery, before they were able to sit up and look at it themselves.

Suggestions for increasing acceptability of the method in future research and clinical practice emerged during pre-testing. Suggestions to use additional methods to remind people to take and transmit their images in order to improve responses were provided by some participants, such as text reminders. In particular, views about the study name ("Selfi") were sought in some of the later interviews. Views on this topic were included following an earlier decline from one patient to take part in the study because of the study name. Findings on the acceptability of the study name were mixed. Some negative attitudes to the name were reported. One participant, for example, reported that they didn't like the association with the popular term "selfie" (that is, a name used to describe an image that someone has taken of themselves, often for the purpose to share on social media), but that it may be more acceptable to younger people. Another participant, however, liked the name and thought it was sensible to have 'Selfi' in the title because "that is what it is" and "conveys what you want it to do".

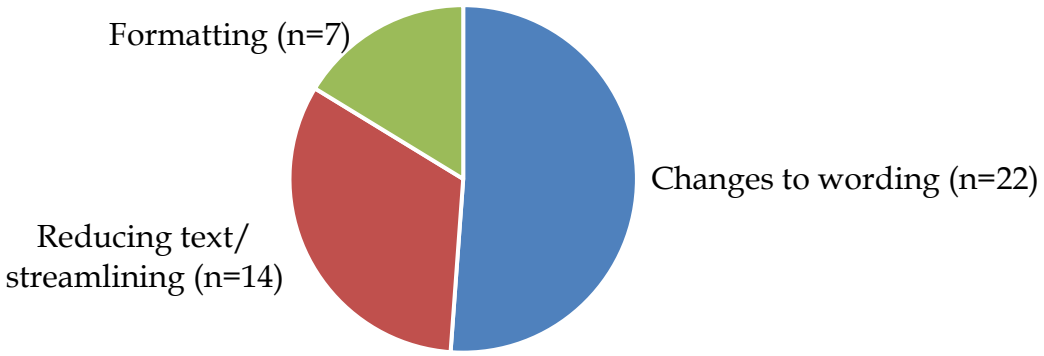
Other topics explored with participants during pre-testing included asking others to help take the wound image. Many talked about asking family members, such as partners or children. Others, however, reported that they would prefer to take the image themselves as they would not want their partner to do it, for reasons related to dignity if the wound was in a personal location on their body. This was helpful to inform consideration for the feasibility and practicality of taking an image in future applications of use with a larger, diverse sample of participants and wound locations.

iii) Revisions to the photography instructions and process for transmitting images

Photography instructions

During the iterative process of pre-testing and refinement, four versions of the photography instructions were produced and pre-tested. A total of 43 edits were made (Figure 5-2). The majority of these were changes to the wording of the items in the instructions (n=22). Other edits were to streamline the instructions by reducing text (n=14) and to make improvements to formatting (n=7).

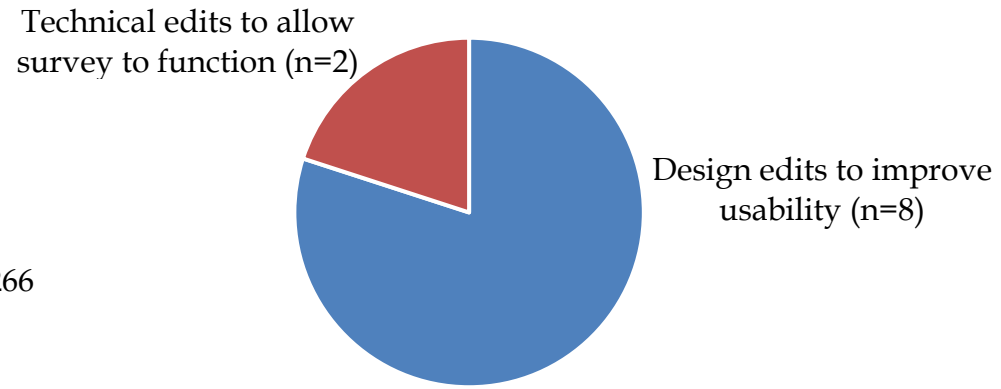
Figure 5-2. Summary of changes made to the wound photography instructions during pre-testing (n=43)



Process for transmitting images

The process for transmitting images was modified four times during the pre-testing phase of the study. Ten edits were made (Figure 5-3). The majority of these edits (n=8) were to the online survey design in order to make the steps for participants to upload images easier to follow. Examples included amending the software to enable participants to see small-sizes (that is, 'thumbnails') of images that they had uploaded on the survey page before they submitted the data. This helped to prevent participants uploading the same image twice in error, when multiple images were intended to be transmitted. Other examples included streamlining text to ensure participants did not need to scroll down the device screen when completing the survey. This was found to be particularly important following observations that some participants did not know how to use the scroll bar on their devices, confirming the recommendations to avoid long survey pages in guidance for designing electronic systems for patients [125,145]. Other edits (n=2) were technical edits, required to make the online survey function as intended. These included the facility for participants to upload multiple images, if required, and an edit to the invitation email to reinstall the link to access the survey following a design error that unintentionally removed it.

Figure 5-3. Summary of changes made to the process for transmitting images during pre-testing (n=10)



5.4. Phase 2 – Evaluation

Phase 2 of the study focused on evaluation of the method for obtaining patient-generated wound images. This involved testing the method remotely with a large sample of patients who had recently undergone surgery. Evaluation included an examination of feasibility, usability, acceptability and image quality. The evaluation phase of the study, called "The Selfi wound study: self-taken images of surgical wounds (Phase B)", ran between January and June 2019.

5.4.1. Assessing feasibility: participant eligibility and recruitment

Eligibility screening data varied in the level of detail provided by the three recruiting teams. Two teams (from centre number 2) did not record the number of patients screened for eligibility, only providing data on the number that were invited and consented (Table 5-5).

Table 5-5. Screening and recruitment data for the evaluation phase of the study

Centre	Recruiting team/specialty	Screened	Number invited	Number eligible	Number recruited	(%)*
1	General surgery	69	62	56	40	(71.4)
2	General surgery	Not recorded	50	46	41	(89.1)
	Vascular surgery	Not recorded	17	14	10	(71.4)
Total			**129**	**116**	**91**	**(78.4)**

*calculated as a percentage of the participants eligible

Data from the study screening logs showed that a total of 129 patients were invited for participation to test the method remotely. Some 10 (7.8%) were further found to be ineligible and 3 (2.3%) were missed for recruitment due to an administration error. Of the 116 eligible participants, 91 (78.4%) consented to take part (Figure 5-4). Reasons why participants were ineligible or declined the study are included in the flow diagram in Figure 5-4, where known.

Two participants were excluded after recruitment. Of these, one participant did not provide contact details at the time of recruitment and attempts to obtain these were unsuccessful, while the other had an extended hospital stay that continued past data collection period of the study. This participant, therefore, was not able to test the method remotely after hospital discharge. Data from the remaining 89 participants were included in the analysis (Figure 5-4). Participant demographics for these 89 participants are presented in Table 5-6.

Figure 5-4. Recruitment flow diagram for the evaluation phase of the study

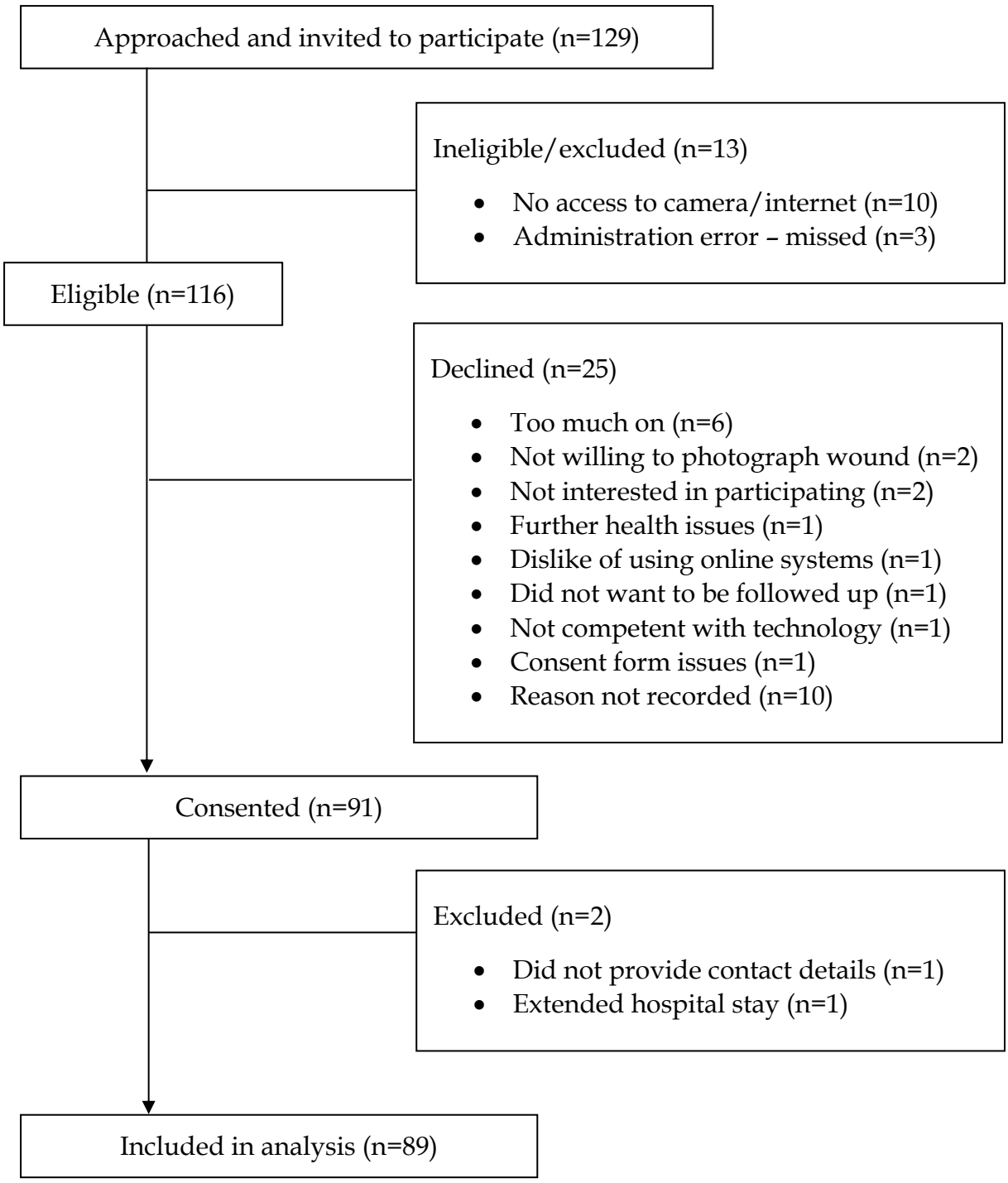


Table 5-6. Participant demographic and operative details (n=89)

Characteristic		
Sex, n (%)		
Male	49	(55.1)
Female	40	(44.9)
Age category, years, n (%)		
18 to 35	26	(29.2)
36 to 50	13	(14.6)
51 to 70	33	(37.1)
over 70	17	(19.1)
Ethnicity, n (%)		
White/White British	87	(97.8)
Asian/Asian British	1	(1.1)
Mixed/multiple ethnic groups	1	(1.1)
Type of surgery, n (%)		
General	81	(91.0)
Vascular	8	(9.0)
Location of wound(s), n (%)		
Abdomen	80	(89.9)
Leg	4	(4.5)
Armpit/Chest	2	(2.3)
Back	1	(1.1)
Groin	1	(1.1)
Neck	1	(1.1)
Number of wounds, median (range)	3	(1 to 6)
Missing	1	
Urgency of surgery, n (%)		
Elective	58	(65.2)
Unplanned	31	(34.8)
Modality of surgery, n (%)		
Open	46	(51.7)
Laparoscopic	39	(43.8)
Mixed*	4	(4.5)

*e.g. laparoscopic converted to open

5.4.2. Assessing usability: effectiveness and efficiency

i) Effectiveness

a) Taking the wound images

There was evidence to show that 52/89 (58.4%) participants completed step one and took an image of the wound (Figure 5-5). Of the 37 (41.6%) participants that did not take an image, it was possible to find out reasons from 16 (43.2%) participants, via reminders or follow-up telephone calls. The main reason for not taking a wound image was non-participation in the study, due to further health problems or life issues (n=11; 12.4%). A minority of reasons (n=4; 4.5%) related to usability of the method, with participants not being able to take an image due to technical/competency issues or practical issues relating to the wound. A breakdown of these reasons is provided in Figure 5-5. A more narrative description is provided under the subheading 'Assessing acceptability' later in this chapter (section 5.4.3). One participant did not take an image as they decided to withdraw from the study. This participant reported that they no longer wanted to take part in the study in reply to a reminder email. They did not, however, provide a reason why they decided to withdraw. For the remaining 21 (23.6%) participants, it was not possible to ascertain whether attempts to take an image had been made as efforts to reach participants by telephone or email were unsuccessful (participants did not answer the phone or reply to messages).

b) Transmitting the wound images

Of the 52 participants that took an image of their wound, 46 (88.5%) completed step two and successfully transmitted the image(s) via the online survey (Figure 5-5). It was possible to elicit reasons why six participants who took wound images but did not successfully transmit them using the online survey, via follow-up telephone calls. For three participants, reasons were due to a low level of competence with using technology; either reporting that they were not proficient in using their device to access the survey online (n=2) or had not been able to find the saved image within their device library when attempting to upload it to the online survey (n=1). These three participants instead sent their images to the author of this thesis, unprompted, by email. This was done as a reply to the automated invitation email to access the online survey, which came from the authors' email address. One further participant was not able to transmit their image due to having no current access to email, and another participant had thought they had transmitted the image. Although other survey data was received from this participant (for example, responses to the debriefing question), no wound images were received. The final participant reported that they had not tried the online survey, without giving a further reason. This participant transmitted the image by email instead. In summary, of the six participants that did not transmit the images using the online survey, images were received by email from four participants (Figure 5-5).

A comparison participant demographics and operative details for those who successfully completed the method and both took and transmitted an image (n=46/89; 51.7%) and those who did not complete either or both steps

(n=43/89;) is reported in Table 5-7. No apparent trend or statistical evidence to support a difference in age, surgery type or wound location between these groups was observed ($p>0.05$ for all comparisons).

Figure 5-5. Flow diagram of participants able to take and transmit images when testing the method remotely

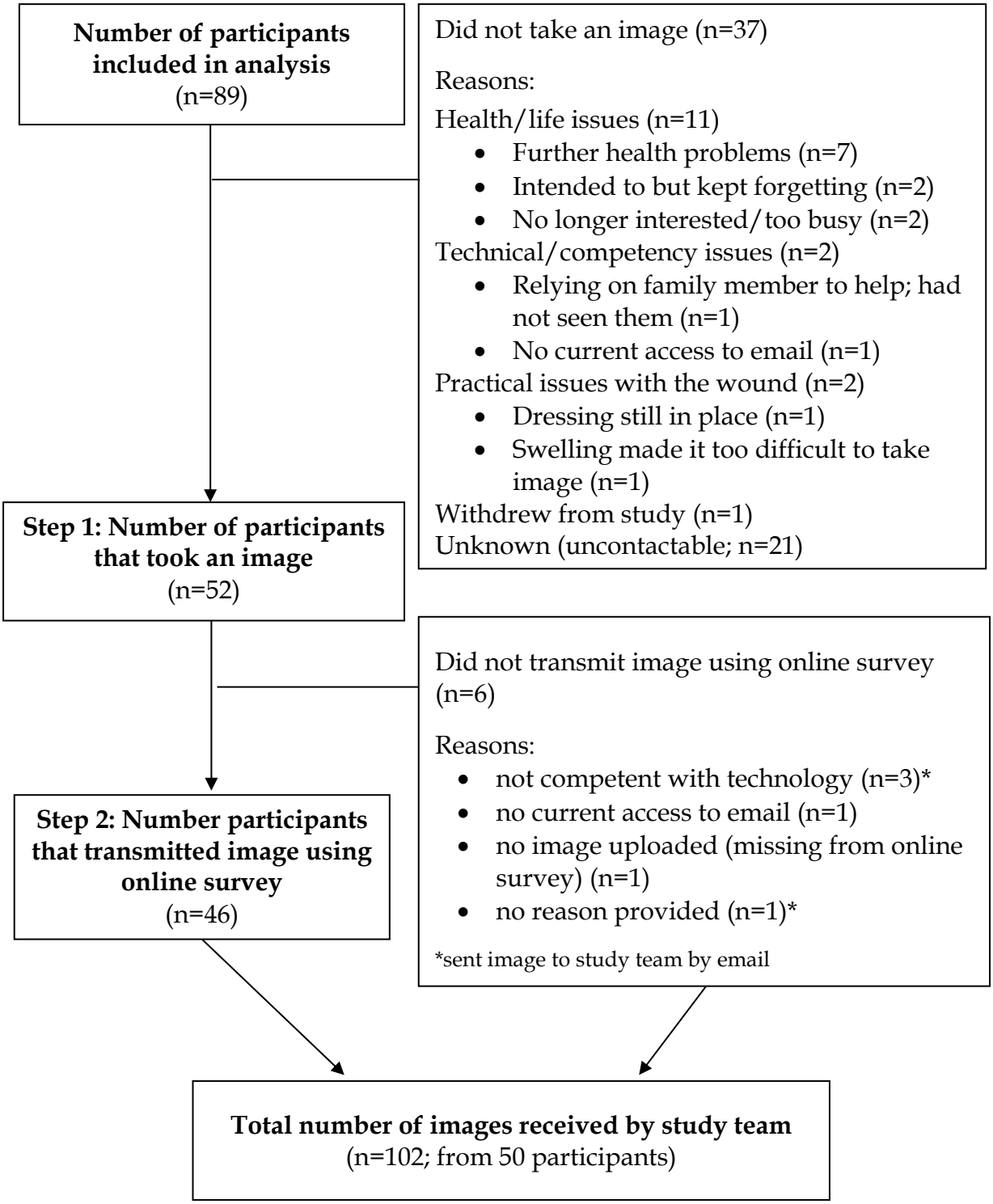


Table 5-7. Demographics and surgical details for participants who completed, and did not complete, the method to take and transmit images.

Characteristic		Participants completing the method n=46	Participants not completing the method* n=43
Sex, n (%)	Male	27 (58.7)	22 (51.2)
	Female	19 (41.3)	21 (48.8)
Age category, years, n (%)			
	18 to 35	13 (28.3)	13 (30.2)
	36 to 50	7 (15.2)	6 (14.0)
	51 to 70	19 (41.3)	14 (32.6)
	over 70	7 (15.2)	10 (23.3)
Ethnicity, n			
	White/White British	45 (97.8)	42 (97.7)
	Asian/Asian British	0	1 (2.3)
	Mixed/multiple ethnic groups	1 (2.2)	0
Type of surgery, n (%)			
	General	43 (93.5)	38 (88.4)
	Vascular	3 (6.5)	5 (11.6)
Location of wound(s), n (%)			
	Abdomen	42 (91.3)	38 (88.4)
	Back	1 (2.2)	0
	Groin	0	1 (2.3)
	Leg	3 (6.5)	1 (2.3)
	Neck	0	1 (2.3)
	Armpit/Chest	0	2 (4.7)
Number of wounds, median (IQR)**		3 (1 to 4)	3 (1 to 4)
Urgency of surgery, n (%)			
	Elective	29 (63.0)	29 (67.4)
	Unplanned	17 (37.0)	14 (32.6)
Modality of surgery, n (%)			
	Open	24 (52.2)	22 (51.2)
	Laparoscopic	19 (41.3)	20 (46.5)
	Mixed/Converted (e.g. lap to open)	3 (6.5)	1 (2.3)
Living status after leaving hospital, n (%)**			
	Living with others	7 (15.2)	5 (11.9)
	Living alone	39 (84.8)	37 (88.1)
Time between surgery and first contact, days, median (IQR)		22 (19 to 28)	22 (20 to 27)

*n=37 did not complete step 1 (taking the photograph); n=6 did not complete step 2 (transmitting the image using the online survey). $p<0.05$ for all comparison between completers vs non-completers.

** Missing data for 1 participant not completing the method. IQR: inter-quartile range.

ii) Efficiency

a) Time taken to obtain images from participants

The median time to respond to the online survey and transmit images was four days after being sent the email invitation (range 0 to 24 days; inter-quartile range one to 10 days).

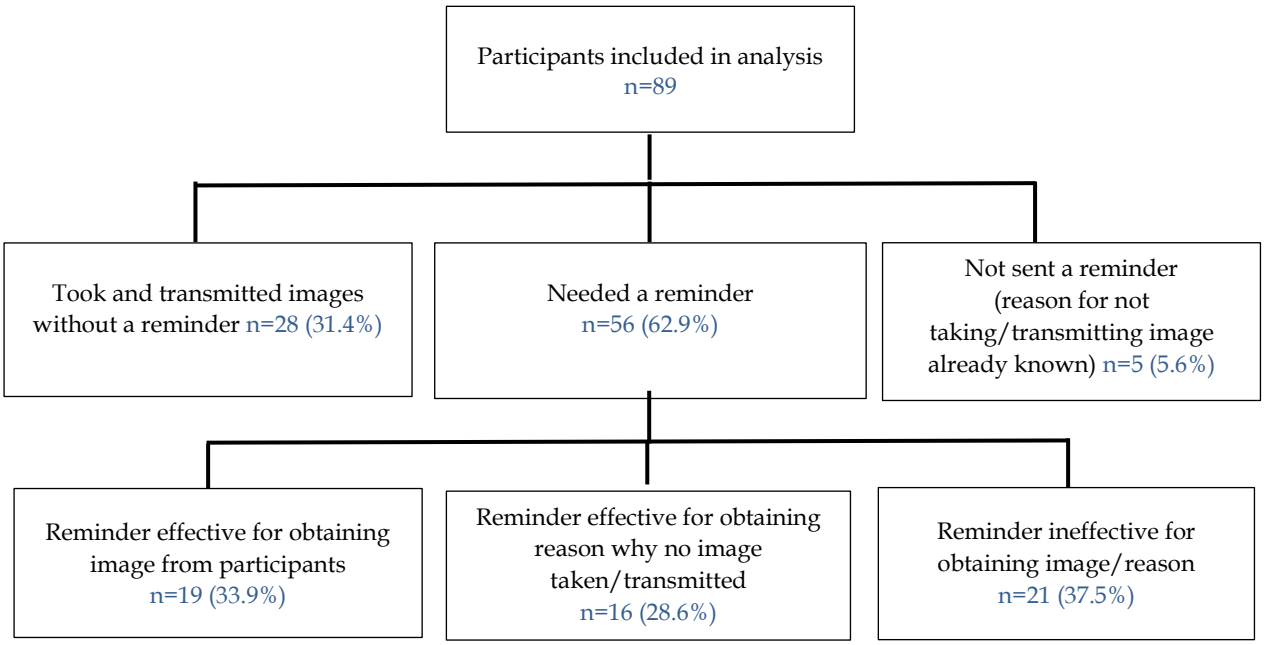
b) The need for reminders

As described in the methods (Chapter 4), participants from whom no images had been received within approximately five days after being sent the invitation email were prompted with a reminder (via either an automated email and/or a telephone call). The exception were five participants for whom the study team already knew of a reason why they had not responded (further health issues (n=2), had an incorrect email address and previous attempts to contact by telephone were unsuccessful (n=1), had sent images by email as had attempted and not been successful in completing the online survey to transmit the image (n=2)).

The number of participants that required a reminder was high. Of the 89 participants that were sent an invitation email, only 28 (31.5%) took and transmitted a wound image without the need for a reminder. A total of 56 (62.9%) participants, therefore, were contacted at least once with a reminder phone call or email. Reminders were effective for obtaining wound images from 19/56 (33.9%) participants, with these participants transmitting images in response to the reminder email or telephone call (Figure 5-6). For 21/56

(37.5%) participants, reminders were ineffective for obtaining an image from participants and it was not possible to ascertain a reason why no image had been received (Figure 5-6). Reminders made to the other 16 (28.6%) participants, however, were successful in receiving a response and provided an opportunity to elicit reasons why they had not taken and/or transmitted images. These have previously been described and are listed in Figure 5-5.

Figure 5-6. Reminders to participants to take and transmit images



c) Time taken to take the wound image

Of the 47 participants that completed the debriefing questions as part of the online survey, the majority (n=41; 87.2%) reported that the process of taking an image of the wound took less than five minutes (Table 5-8). Only one (2.1%) participant reported that it took more than 15 minutes to take the photograph(s). It was possible to find out more information during a follow-up telephone call. The participant reported that the time was increased because their wounds were small in size and in a difficult location on their body (the neck) for them to photograph themselves. They asked their partner to help, however, the partner was not experienced with using the mobile device and it therefore took a long time to take a suitable image.

d) Help from others to take/transmit images

Debriefing questions within the online survey collected data on the requirement of help to take and transmit images (Table 5-8). Of the 47 participants that completed the online survey, the majority (n=25; 53.2%) reported that someone else took the wound images. Reasons for why someone else took the images were not routinely collected as part of the study. The participant information leaflet and the photography instructions did state, however, that it was acceptable to ask someone else to take an image. Some 19/47 (40.4%) participants reported that they took the images themselves. The remaining three participants (6.4%) reported taking some photographs themselves while someone else took others (the participants had more than one wound).

Few participants 8/47 (17.0%) reported that they needed help to transmit the image (Table 5-8). All of them asked a family member. Specific reasons that help was needed was not collected as part of the online survey. One participant who reported that they needed help with transmitting the images on the online survey took part in a follow-up telephone call. The reason they asked their partner to help was because they were more familiar with technology (which they described as "tech-minded"). This participant had not attempted to transmit the image themselves.

Table 5-8. Participant burden to take and transmit images: time taken and requirement for help reported in the online survey

Debriefing item	**n**	**(%)**
Time taken to take the wound image, minutes		
Less than 5	41	(87.2)
5 to 10	5	(10.6)
10 to 15	0	0
More than 15	1	(2.1)
Help with taking the image		
Yes	25	(53.2)
No (self-taken)	19	(40.4)
Mixed (participant plus another person took images)	3	(6.4)
Help needed to transmit the image		
No	39	(83.0)
Yes	8	(17.0)

5.4.3. Assessing acceptability: participant feedback and experiences

Participant feedback and experiences with taking and transmitting images were collected in two ways. These were: i) free text space within the online survey (used by 8/47 (17.0%) participants), and ii) follow-up telephone calls to a sub-sample (n=13; 14.7%) of participants. A third, unanticipated source of feedback was obtained during reminder phone calls to participants who had not transmitted images within a week. During these reminder phone calls, participants provided feedback and reported where there had been problems with taking or transmitting the wound images.

Feedback was categorised as either: i) positive or ii) describing problems encountered when taking and/or transmitting images. Problems were further categorised as: a) wound-related problems and b) technical/technical competency issues. A descriptive account of the feedback in relation to these different categories is provided below.

i) Positive feedback

Nine participants (five using free text space within the online survey and four participating in a follow-up call) described the process of taking and transmitting the images as easy and straightforward. Verbatim quotes are included in Box 10.

Box 10. Positive feedback reported by participants

Quotes reported in free text space in the online survey (n=5):

- *"Was not a difficult process at all."* [participant B020]
- "*Everything went smoothly."* [participant B030]
- *"It was a very easy process!"* [participant B042]
- "*Easy to do, I think it's an excellent programme and should be introduced to all patients."* [participant B050]
- "*All pretty straightforward"* [participant B034]

Positive experiences described in follow-up calls (n=4).

- *"Easy to do"*
- "*Easy"*
- "*Instructions were clear"*
- "*Straightforward to follow"*

ii) Problems encountered when taking or transmitting images

Participants' reports of problems encountered or issues with taking or transmitting images are summarised in Table 5-9. Many of these reported problems, however, were overcome, with only four resulting in participants not being able to take or transmit an image at all. Where the problems had resulted in participants not being able to take an image, information was included in the study flow diagram above (Figure 5-5).

Table 5-9. Summary of participant feedback of problems

Component	Category of problem/issue	Specific problem (number reporting a problem)
Taking the image	Wound-related	• Difficult location of wound (n=3) • Dressings in place for prolonged length of time (n=2) • Swelling (n=1)
	Technical competence	• Did not have anyone technically capable to help (n=1)
Transmitting the image	Technical competence	• Problems transmitting image due to inexperience with technology (n=3) • Problems finding the image on device (n=1)
	Technical	• Problems with the online survey crashing (n=1)

a) Wound-related problems

Location of wound on the body

Location of the wound was a particular problem for a small number of participants, as reported in free text within the online survey (Box 11). In a reminder phone call, one participant described how they had not taken a photograph as the location of their wound, and surrounding swelling, had made it difficult. They had not wanted to ask a family member to help because they wanted to protect their dignity.

Box 11. Participant feedback in the free text space in the online survey about difficulties with wound location

- *"Taking the selfi of my abdomen was quite difficult."* [participant B041]
- *"I got my partner to take the photos for me as I had difficulty seeing my phone camera screen on account of where the wounds were situated."* [participant B039]
- *"Impossible to take photos myself* [due to location of wound] [participant B013]

Dressing use

During reminder phone calls, two participants reported that they had not yet been able to take images due to dressings still being in place. One participant's wound was still covered with a dressing five weeks after surgery and they had not attempted to take a photograph because of this. For the other participant, dressings were still required after hospital discharge and

dressing changes were being undertaken by a district/practice nurse. This participant successfully took an image after the dressing had been removed, although this meant that the transmission of the image was delayed.

b) Technical /technical competence issues

Four participants sent their images by email rather than transmitting them using the online survey, as previously described. These participants were followed up with a telephone call to elicit reasons. Of these participants, two had attempted to transmit the images via the online survey but had been unsuccessful: one reported that they had not been directed to the filestore on their device when prompted to select and upload an image and the other reported that they had tried the online transmission but "couldn't quite remember what had happened", also reporting that they were "not very good with computers". The remaining two participants had not attempted to transmit the images via the online survey. One had not noticed the hyperlink in the invitation email and the other did not provide any explanation.

One further participant reported that they had had technical difficulties with transmitting an image (Box 12). A follow-up telephone call with this participant discovered they had found the whole process difficult. The wound was small and in a location that made it hard to see the device screen when taking the image themselves. They were not able to get help from their husband as he was not experienced with using the mobile device. They did, however, manage to take and transmit four images. The images were slightly blurry but were all rated sufficient for potentially assessing the wound for SSI in the analysis of image quality (described later in this chapter). This participant reported that they thought younger people might find the process easier.

Box 12. Participant feedback of technical difficulties with transmitting images

> *"Couldn't upload from mobile; link kept crashing. I think if I hadn't agreed to take part in the research I would have given up."* [participant B013]

From the total number of participants testing the method remotely (n=89), one participant had completed the online survey and provided other data (such as the debriefing questions) but no wound image. Feedback via a follow-up call was sought to elicit further information and whether any problems had been encountered. The participant reported they had taken an image and had thought they had transmitted the image via the survey. To their knowledge, no problems had been encountered.

5.4.4. Assessing image quality

A total of 102 images were received from 50 participants. This was because the majority of participants (n=43; 48.3%) had more than one wound (Table 5-6). All images were assessed for quality. Judgements on their suitability for potentially making a clinical assessment of the wound for SSI were made by three independent clinical assessors.

Judgements of sufficient / insufficient images

The majority of images (n=84 to 88; 82.4% to 86.3%, depending on the assessor) were considered sufficient to assess the wound for surgical site infection. An example of a wound image submitted by a participant and judged as sufficient by all three assessors is illustrated in Figure 5-7. The number of images judged as insufficient were between 14 (13.7%) and 18 (17.6%), depending on the assessors Table 5-10.

Figure 5-7. Example of a clear, standardised wound image submitted by a participant

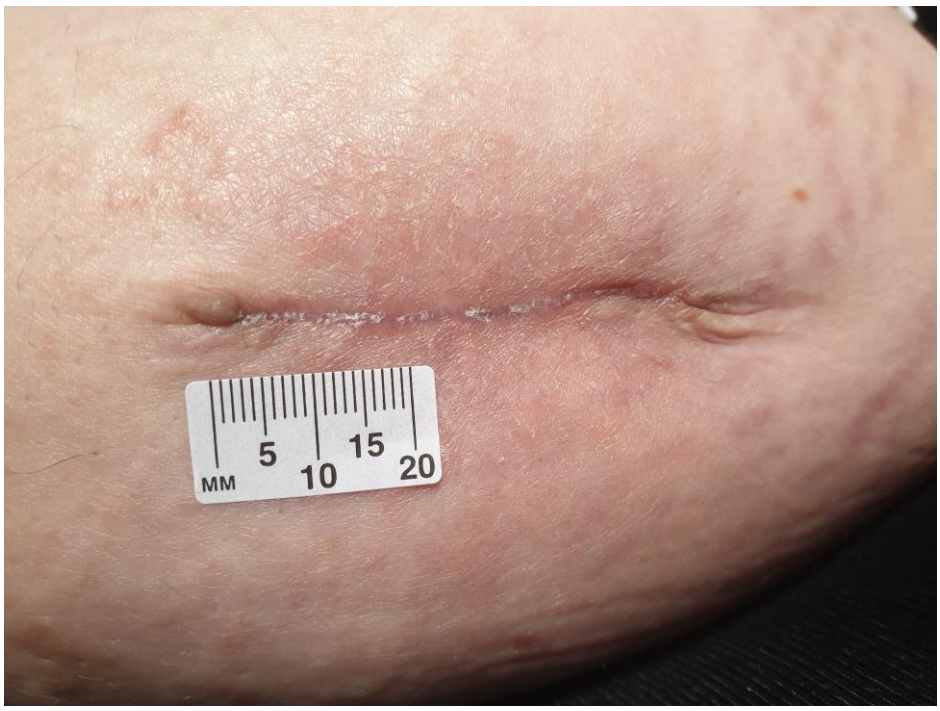


Table 5-10. Judgements of image quality by the three independent assessors

Assessor	Sufficient image n (%)	Insufficient image n (%)	Total
1	88 (86.3%)	14 (13.7%)	102
2	84 (82.4%)	18 (17.6%)	102
3	88 (86.3%)	14 (13.7%)	102

Inter-rater agreement on judgements of image quality

A comparison of assessors' judgements of whether an image was sufficient quality for potentially assessing the wound for SSI demonstrated 85% overall agreement and a Krippendorff's alpha co-efficient of 0.41, suggesting moderate agreement. Of the 102 images, 87 (85.3%) were considered to be sufficient quality by at least two of the three assessors and 75 (73.5%) were unanimously considered to be sufficient quality by all three assessors (Figure 5-8). Only four (3.9%) images were considered insufficient by all three assessors. These images came from four different participants.

Figure 5-8. Agreement between assessors for judgements of image quality

Assessors' reasons for judging images as insufficient quality

Assessors' judgements of insufficient images were categorised as i) reasons that could be improved with modification to the photography instructions and ii) reasons that could not be improved with modification to the photography instructions (Table 5-11). Reasons that could be improved with modification to the photography instructions (applicable to 19/102 (18.6%) images) included: poor angle, poor focus, presence of shadow, too dark, over-exposed, full wound not visible within the image, full extent of redness surrounding the wound not visible within the image.

Reasons that could not be improved with modification to photography instructions (applicable to 8/102 (8.8%) images) related to where the wound was on the body. In all cases, these were images where wounds included the umbilicus cavity (belly button) and where part of the wound was hidden within this cavity. For these participants, it would only have been possible to photograph the full wound if the skin was pulled down and held taut, which would not have been suitable to include in the photography instructions for patients due to risk of introducing infection or potential damage to the wound. Full examination to adequately view and assess the wound in these cases would require manipulation of the skin by clinical staff rather than a patient and would be more appropriate for a face-to-face assessment. These wounds, therefore, are potentially less suitable to assess using a photograph.

Table 5-11. Reasons for assessors' judgments of insufficient image quality (n=27)*

Category	Number of images†	Detailed reason (number of images)
i) Reasons that could be improved with modification to photography instructions	19	Poor focus (n=9) Full wound not visible within image and no further image provided (n=8) Shadow over the wound (n=4) Poor angle (n=2) Too dark (n=1) Over exposed (n=1) Extent of redness not visible as continued outside of image frame (n=1)
ii) Reasons that could not be improved with modification to photography instructions	8	Part of wound not visible as inside belly button (n=8)

* by any one of three assessors
†Some images were judged as insufficient for more than one reason

A sensitivity analysis to examine assessors' agreement of image quality, excluding images that were judged as insufficient for reasons that could not be improved with modification to the photography instructions (n=8), indicated greater agreement between assessors (89% agreement; Krippendorff's alpha of 0.51).

5.5. Discussion

This chapter reports the findings from the development and evaluation of a method for patients to take and transmit images of their wound after leaving hospital for remote SSI assessment. Findings are reported in two study phases: first the development and pre-testing of the method, and second, its evaluation for intended use in future research or clinical practice.

The first study phase included a content analysis of 11 existing documents relevant to taking standardised wound images photography (one guideline for medical illustrators, seven published papers and three study protocols using images for outcome assessment). Some 21 key features were identified and considered for the development of wound photography instructions for patients, ensuring they were relevant for patients to take standardised wound images after leaving hospital using their own mobile device. A process for patients to transmit images in the form of an online survey using existing IT software was developed, ensuring it was suitable for patients to access and upload images using their own device. Some 16 cognitive interviews with observation were conducted with patients to pre-test the photography instructions and process for transmitting images. Potential issues were identified and addressed with modifications and revisions to the photography instructions and transmission process.

The second phase of the study undertook an evaluation of the method developed and pre-tested in Phase 1. Participants were recruited to test the method remotely. Findings were analysed to examine feasibility, usability,

acceptability and quality of the images. Obtaining images remotely was found to be feasible and acceptable to the majority of participants in the study, with 91/116 (78.4%) approached and eligible patients consenting to take part. A number of participants did not complete the study for reasons such as further health problems or not having time/no longer being interested in taking part (n=11; 12.4%). A small number of problems were reported in taking or transmitting images, with a minority or participants (n=5) experiencing problems with technology or competency issues with using their devices to take or transmit images. For six participants, issues relating to the wound itself were problematic for taking an image, such as where the wound was located on the body or continued use of dressing for a prolonged period of time. Many of these problems, however, were overcome, with only four (4.45%) participants unable to take or transmit an image of their wound at all. Some 21 (23.6%) participants, however, did not complete the study and it was not possible to ascertain the reasons because attempts to contact participants were unsuccessful. Of the 102 images that were obtained from participants, image quality was high, with 87 (85.3%) images judged as sufficient to assess the wound for SSI by at least two of three clinical assessors.

5.5.1. Strengths

The development and evaluation of the method for patients to take and transmit wound images combined methodology from two approaches. This included established methods drawn from the field of PROM development and validation, to ensure the photography instructions for patients had relevant and appropriate content to produce a suitable image and were comprehensive and easy to understand. Established methodology for testing

digital systems were also applied, to reflect the human-system interaction required for patients to perform the method of taking and transmitting images. Rigorous pre-testing using face-to-face cognitive interviews with observation was conducted to ensure the method was acceptable and fit for purpose before testing in a large sample of participants from the target population. Further strengths of the study include the purposive sampling, to include a diverse spread of participant ages, wound locations and types of surgery to maximise generalisability of the study findings. The photography instructions and process for patients to transmit images are reproducible, making them suitable for adoption in future research and clinical contexts.

5.5.2. Limitations

Analysis of feasibility

Analysis of the feasibility of the method to take and transmit images was limited to some extent in the current study. Whilst there were attempts to collect data on the number of patients suitable for the study, screening data was found to differ across the recruiting centres. This meant that accurate data on the number of patients that were ineligible were unavailable. Problems with poorly reported screening data is common in research studies [146]. Although a high number of those approached consented to the study and had the appropriate device to take and transmit an image after leaving hospital, it is unknown whether this is reflective of the wider population. In future, however, it is likely that more of the population will have access to and be familiar with taking and transmitting images using digital devices. The evaluation of feasibility in relation to the wider population may be

limited at present, although it is likely that the method will be even more feasible for future populations, because of the anticipated increase in the use and ownership of digital devices [72]. Efforts to collect accurate screening data warrants more attention in future studies to adequately assess the feasibility of the method in a wider context.

Timing of outcome assessment and wound photography

The evaluation of the method to obtain wound images is limited to a request for patients to take and transmit images on a single occasion, typically several weeks after the patient had left hospital following surgery. Findings demonstrated that taking images of wounds sooner after leaving hospital may incur more problems as it may be difficult for patients to take images if dressings were still in place. This may have implications for using this method to monitor wound healing in 'real-time' or on a regular basis immediately after leaving hospital. Findings are currently limited to evaluation of this method at a single timepoint two-to-three weeks after surgery and it is unknown whether use of the method for obtaining images sooner after leaving hospital is feasible. Further work to explore this is warranted.

The next and final chapter will bring together the two studies conducted within this PhD work. It will discuss the work in the context of recent literature and its strengths and limitations. Applications of the new outcome measure and the method for obtaining wound images from patients for remote SSI assessment in research and routine practice are considered, including areas for future research.

CHAPTER 6. DISCUSSION

6.1. Introduction

This thesis reports on research to improve SSI outcome assessment. It focuses on SSI data after the patient has left hospital. Two distinct but related studies were undertaken. The first study developed and validated a new outcome measure for SSI to be completed by the patient or healthcare professional. The second study explored a method for patients to take and transmit digital images of wounds for remote SSI assessment. The intention was that these methods would be complementary and reproducible for use in future applications. Whilst the concept of this work originated within the context of a research study, as the work developed it became evident that there was potential application in routine surgical follow-up, research and audit. This chapter will now discuss the work. First, the study findings will be summarised and considered in the context of recent literature. Next, the work will be critically evaluated, discussing the strengths and weaknesses. Finally, opportunities and recommendations for future work will be discussed, including plans for further research.

Summary of the rationale for the research

Surgical site infection continues to be a significant problem for healthcare worldwide [11,16]. Accurate and reliable SSI assessment is needed for routine

surgical follow-up, research and audit. Data are needed to effectively evaluate interventions aimed to reduce SSI, and for benchmarking and priority setting in the healthcare service [20,21]. Accurate SSI assessment, however, is challenging because of the changing nature of care and the drive for shorter hospital stays, meaning that the timing of appearance of SSI is often when the patient has left hospital [18]. This has implications for research and routine surveillance. Follow-up visits with patients to assess symptoms and signs of SSI can be resource intensive, logistically difficult and costly to both patients and the health service [26].

Before this research began, there was no outcome measure for SSI that had been developed and validated specifically for use after hospital discharge. Existing tools for assessing wounds included checklists of 'SSI criteria' based on SSI definitions and grading scales with either no or minimal validation [31]. These existing tools have limitations. They were designed for completion by healthcare professionals, primarily for use in-hospital and they are complex to complete [38]. In addition, they have been criticised as being too subjective, meaning SSI diagnoses are dependent largely on the views of the person assessing the wound. As a result, SSI diagnoses have been shown to be inconsistent and their data unreliable [36,54]. No patient-reported outcome measure has previously been developed. Use of the existing clinician-completed tools relied primarily on a face-to-face assessment of the wound, which could be logistically challenging for patients travelling long distances or needing to take time off work, resource-intensive for healthcare staff and costly to both patients and the health services. Face-to-face assessments may often be unnecessary if the wound is healing with no problems. Alternatively,

timing of face-to-face assessments may be too late to recognise and treat early signs and symptoms of SSI, risking the severity of problems getting worse. Remote assessment of wounds using electronic transmission of patient-generated digital images was an emerging area at the time of starting this research. Studies, however, had paid little attention to instructions for patients on how to photograph the wound to ensure that the image was fit for purpose.

Summary of study aims

The aims of this research were to address the limitations of existing methods and measures for SSI. Two aims were specified:

1) Develop and validate an SSI outcome measure for patient or healthcare professional completion, suitable for use after the patient has left hospital
2) Develop and evaluate a method for patients to take and transmit a standardised image of their wound after leaving hospital, for remote wound assessment

These aims were addressed in two studies.

6.2. Summary of the studies and key findings

6.2.1. Study 1

Development and validation of a new SSI outcome measure

The development and validation of a new SSI outcome measure is reported in Chapters 2 and 3 (methods and results, respectively). This work has been published in peer-reviewed journals [147,148] (Appendices 1 and 2). It has also been published as part of an NIHR HTA monograph reporting the wider Bluebelle feasibility study [1]. The development and validation work included a series of study phases to ensure that the new measure was reliable and valid for assessing wounds for SSI after patients had left hospital. The essential properties of an outcome measure were addressed, in accordance with established and widely-used methods for PROM development and validation [46,85,86]. Specifically, these properties included content, construct and criterion validity, reliability and acceptability. Key findings related to these measurement properties are summarised below.

Content validity

The final outcome measure comprised 18 items to assess a comprehensive set of domains relevant to assessing wounds for SSI. One of the domains, smell, was identified from interview data. This is not a criterion included in other commonly used definitions or grading scales [149]. Some bacteria that cause

infections, such as gram-negative and anaerobic bacteria, can create foul odours due to tissue breakdown [150]. Although it is recognised that not all infected wounds produce a smell and different types of bacteria produce odours of different types [151], smell was identified as an important domain in the assessment of wounds for SSI and relevant to include in the new measure.

Novel methodology using lay language alongside medical terminology in items was employed in this work. This novel approach to questionnaire design was developed as part of this PhD. The use of medical terminology alongside plain language was found to influence the way an item was interpreted. It provided, therefore, a method for ensuring content validity; to make sure items accurately reflected the underlying domains intended to be measured. The discovered benefits for improving content validity have been published [152] (Appendix 3). The publication describes the new type of measure, applicable when the health issue of interest can be assessed by either the patient or an observer, calling it a 'universal-reporter outcome measure' (UROM). This type of measure is applicable for gathering information or opinions from patients and healthcare professionals on the same subject, such as Delphi surveys to prioritise outcomes for a core outcome set (COS) [153,154]. Where appropriate, the use of medical terminology alongside plain language as pioneered in the current study is now endorsed by the Core Outcome Measures in Effectiveness Trials (COMET) initiative and is included in guidance for the development of COSs [155].

Language in the new outcome measure referred to 'wound healing' rather than 'infection'. This was based on findings from the interviews that patients did not always refer to the word infection to describe their wound problems or experiences. This finding is supported in other published literature. A qualitative study exploring patients' experiences of SSI, for example, found that patients were not always aware that they had had a wound infection when one had occurred [156]. The choice of words for items in an outcome measure is crucial to ensure that they are comprehensible to the target population and acceptable so that people are willing to complete it and data are reliable [45,46]. Indeed, if the word infection is included in the title, instructions or items of a measure and patients did not think it was relevant to them, it may result in the questionnaire being dismissed and not completed at all.

A range of response categories allowed the severity or extent of a symptom to be reported in the new outcome measure, further strengthening its content validity. The importance of this is reflected in other studies that have explored the important factors for defining SSI. In a study by Sanger et al., for example, a prognostic model of SSI using daily wound assessments demonstrated that the amount of exudate was more strongly associated with SSI than the type of exudate [157].

Construct validity

Construct validity was demonstrated by examining the underlying structure of the data, and whether responses to items clustered together to reflect a unidimensional (single scale) SSI construct or a more complex multi-dimensional construct. Analyses supported the proposal that a single scale/factor model was the best fit for the data, suggesting that SSI could be measured as using a single scale that made clinical and practical sense. Internal consistency of the single SSI scale was good, with Cronbach's alpha coefficients of 0.86 and 0.88 in participant self- and observer-assessment data, respectively [46].

Criterion validity

Criterion validity was examined by comparing participants' self-assessment total score on the new outcome measure with a reference SSI assessment. The reference assessment of SSI or no SSI was determined from a face-to-face assessment with a healthcare professional using the CDC criteria and definition for SSI. The outcome measure demonstrated good criterion validation. A ROC curve analysis showed high sensitivity and specificity for SSI discrimination compared to the reference CDC diagnosis.

Reliability

Test-retest reliability was demonstrated to be good for the majority of items. Observed agreement between the test and re-test responses was more than 86% for any of the items. Reliability of the measure as a patient self-reported tool was examined by comparing participants' responses with data from the

observer-completed assessment. Agreement between self- and observer assessments was generally high. A trend for patients to report signs and symptoms a little more severely than healthcare professionals was observed, although the difference was small and not significant. The trend was seen in the lower end of the response categories, with a tendency for patients to report mild signs or symptoms whereas the healthcare professionals reported the sign or symptom as not being present. This observation is supported in previous studies, where a similar minor discrepancy in patient and healthcare professional reports of symptoms has been reported [158-161]. Some slight discrepancy in reports of whether wound care interventions had occurred were observed, although the number of occurrences of the intervention were too few in the sample to draw any inferences from this observation.

Acceptability

The measure was demonstrated to be acceptable to patients and healthcare professionals. Cognitive interviews confirmed that patients and healthcare professionals were willing and able to complete the measure and that the item language, questionnaire length, format and response categories were appropriate. Acceptability of the use of plain language alongside medical terminology was confirmed. In the field-testing study, levels of missing data to individual items were low. The exception were some sub-items, where responses were often missing when they were expected to have been completed. These responses were likely to be missing in error as a result of the formatting of the questionnaire. Formatting was improved to avoid this issue in a revised final version of the measure. Feedback from participants who were asked to complete debriefing questions) showed that it was quick

to complete with few problems. There were no complaints about the length or content of the questionnaire from patients or health professionals.

6.2.2. Study 2

Development and evaluation of a method for remote wound assessment using patient-generated digital images

Study 2 developed and evaluated a method for patients to take a digital image of their wound and transmit it to a research/healthcare team for remote assessment after leaving hospital. The study was conduct in two phases: 1) development of the components of the method (that is, wound photography instructions and the process for transmitting images) and 2) evaluation of the feasibility, usability and acceptability of the method for SSI assessment in future applications of its use, including an evaluation of image quality.

Content validity and acceptability

Content validity of the photography instructions was addressed by undertaking an analysis of existing wound photography literature to identify the important features for photographing wounds. Some 21 key features for photographing wounds (for example, patient positioning, lighting) were identified. These were formulated into instructions for patients, suitable for use after leaving hospital using cameras on their own mobile device. Existing IT software was adapted to design an online survey with a facility to upload images, as a process for patients to transmit their images using their own

mobile device. An iterative process of pre-testing and subsequent modifications to the photography instructions and transmission process ensured that both components were comprehensive, comprehensible, and acceptable to patients. Participants generally supported the idea of taking and transmitting images after leaving hospital with few problems envisaged.

Feasibility, usability, acceptability and image quality

The second phase of the study focused on evaluation of the method for remote SSI assessment in future applications of its use. Patients undergoing surgery were invited to take part in a study to test the method remotely and take and transmit images of their wound after leaving hospital. Screening and recruitment data demonstrated the method was feasible, with 91/116 (78.4%) approached and eligible patients consenting to take part. The number of participants effectively taking and transmitting images was 52/89 (58.4%) and 46/89 (51.7%), respectively. Where it was possible to ascertain reasons from participants for not taking or transmitting and images, reasons were primarily further health problems or low priority of the study compared to other demands in participants lives (n=11; 12.4%). Only a small minority (n=4; 4.5%) of participants experienced practical problems with photographing the wound, or technical or competency issues with transmitting the image that made it impossible to take or transmit an image at all. Efficiency of the method was demonstrated with participants transmitting images a median of four days after being requested. Responses from participants answering debriefing questions found that the process was quick to do with few problems reported. Some problems with taking images when the wound was in a difficult location or when a dressing was in place were described,

although many of these problems were overcome and it was possible to take an image with help from others. Quality of the images was generally very high. Some 87 (85.3%) images were judged to be adequate for potentially assessing the wound for SSI by at least two of three independent clinical assessors.

6.3. Findings in the context of recent literature

A novel contribution to SSI assessment

Recent literature demonstrates that accurate SSI outcome assessment continues to be a problem. The challenge of assessing wounds after the patient has left hospital means that data are unreliable and estimates of SSI rates are uncertain. Research to develop a reliable and valid measure for SSI suitable for patient self-report after leaving hospital was welcomed [44,57]. When the current PhD work describing the development of the new outcome measure was published in the Journal of Infection Prevention in 2017, for example, the journal editor wrote an accompanying editorial endorsing the work and methodology to include patients in the development and testing of the measure. The editor wrote that "finding robust methods of identifying infections after the patient has been discharged from hospital is critical to measuring the risk of SSI". The editorial described how the development of the outcome measure addresses a key problem for SSI surveillance systems where reliable measure to identify SSI after the patient leaves hospital are needed [14].

Further highlighting the ongoing problem in obtaining accurate SSI data after the patient has been discharged, a 2018 commentary in Lancet Infectious Diseases described the difficulties with achieving in-person wound reviews for obtaining accurate SSI outcome data in large trials [162]. The authors went

on to describe how novel methods using mobile devices to collect data, including images from patients, could make remote follow-up possible. More recently in October 2019, an entire special issue devoted to methods and technologies for assessing surgical site infection was published in Surgical Infections [163]. Papers emphasised the potential for using patient-generated data on symptoms and signs of SSI, including patient-provided images, discussing recent advances and future directions for SSI surveillance in research and clinical practice [62,75,78,120,164-169]. Of specific relevance to the current work, one of the papers in the series describes how patient-generated data, including digital images, may improve the consistency and precision of SSI diagnosis, citing the work conducted in this PhD [120].

The need for better measures and methods for SSI assessment after hospital discharge was further demonstrated at the 11th Healthcare Infection Society International conference in 2018. In a debate entitled "National surgical site infection surveillance – friend or foe?", speakers on both sides of the argument described the limitations of the existing tools available to assess SSI and the particular difficulties in obtaining accurate data post-discharge, emphasising how this had implications for UK hospitals reporting SSI rates. Concerns remain that the true scale of SSI rates is unknown due to a lack of adequate and reliable data. All these examples demonstrate the timeliness and relevance of the work conducted in this PhD and the urgent need for improved methods for SSI outcome assessment, particularly after patients leave hospital.

Since commencing this PhD, the author of this thesis has become involved in networks and working groups of academic and clinical experts in this field. Specifically, these are the Wounds Research Network (WReN) and the NHS England National Wound Care Strategy Programme (NWCSP) [25,170]. More detail on the author's involvement in these groups and how it has helped dissemination and uptake of this PhD work will be described later in this chapter (section 6.6). The WReN includes surgeons, wound infection control practitioners, tissue viability nurses and researchers involved in wound care across the UK and provides a platform for shared learning and support for all types of wound research [170]. The NWCSP includes clinical and academic experts in pressure ulcers, lower limb ulcers and surgical wounds. Empirical evidence found through involvement in these groups has confirmed that no new SSI measures have been developed, and the CDC diagnostic criteria and ASEPSIS grading scale remain to be the tools that are widely used. This includes use by the UK government agencies PHE and NICE [22,90]. This is supported with evidence from more recent Cochrane systematic reviews, which demonstrate that the CDC criteria are still the most widely used tool for defining SSI in clinical trials [20,117]. For example, The Getting it Right First Time (GIRFT) programme, an initiative funded by the Department of Health in 2016 to reduce infection rates in the NHS, collects data on SSI rates across hospitals in the UK and uses the CDC criteria to define SSI [23]. It has been criticised, however, because the methods to collect data within the programme are largely reliant on hospital data and use of sub-optimal tools based on the CDC criteria. There are concerns, therefore, that despite this recent initiative, SSI rates will continue to be an inaccurate reflection of the true situation. The author of this thesis has attended specialist wound care

conferences throughout the course of this PhD. There have not been any other contributions presenting new SSI tools.

In light of the recognised problems with existing methods and measures for SSI, this PhD work has produced two novel contributions to improve SSI outcome assessment. The new outcome measure, specifically designed for use after the patient has left hospital, is the first SSI outcome measure to be developed that can be completed by patients or a healthcare professional. It has been developed and validated with robust methodology, providing a much-needed tool for research and routine practice where existing tools are sub-optimal. Indeed, it is evident that clinicians and researchers are not satisfied with the existing tools available for assessing wounds for SSI. Since the findings from this study have been published and disseminated at conferences and via research networks, there has been a great deal of interest in using the new outcome measure, indicating its value to the field. As of March 2020, published papers and conference abstracts reporting the development and validation work of the new outcome measure have been cited a total of 13 times. Further evidence for the need for this work is demonstrated by the number of requests to use the new outcome measure. At the time of writing this thesis, the number of such requests has reached 30, including use in both research studies and routine follow-up. This has included international requests from Switzerland, the Netherlands, Australia, US, Turkey, Kosovo, Myanmar and Malaysia. In the UK, seven grant applications for studies that include the new measure to collect outcome data have been funded. New studies using the measure include RCTs exploring dressing interventions to reduce SSI in emergency laparoscopy (the NIHR

RfPB-funded SUNRRISE trial; PB-PG-0416-20045), multiple interventions to reduce SSI in general abdominal surgery (the NIHR HTA-funded ROSSINI 2 trial; 16/31/123), negative pressure wound therapy for wounds healing with secondary intention (the NIHR HTA funded SWHSI 2; 17/42/94) and a trial of fibrin sealants in head and neck cancer surgery (part of an NIHR-funded doctoral research fellowship: the DEFeND trial). More details of these studies are described later in this chapter. Recruitment to these studies has started and data collection using the new outcome measure is ongoing.

Recent literature has been published reporting other peoples' work on wound photography that is relevant to this PhD research. As described in Chapter 1, existing studies exploring the use of patient-generated wound images lack detail on how the photography instructions for patients, if any, were developed or provided. Since starting the current research one study has subsequently been published that includes instructions for patients to take a wound image [71]. No detail, however, is included on how the instructions were developed and how their content was informed. The current study has paid attention to this issue, to ensure the images of the wound are suitable and of sufficient quality to be clinically usable to assess the wound for SSI.

Work looking at patient-generated wound images continues. In the US, for example, a Health Technology Assessment of the current use of mobile health (mHealth) for SSI care, called the Assessing Surgical Site Infection Surveillance Technologies (ASSIST) project, was undertaken and published in 2019 [75,76]. In contrast to the current study, many of the studies identified by the ASSIST project involved the development of an app to collect images.

Recent published literature and ongoing research in the US further demonstrates work surrounding the collection of patient-generated SSI using a mobile phone app [164,165]. The method for obtaining patient-generated images in the current study, however, intentionally did not involve the development of an app. Instead it utilised existing IT software and the cameras on patients' own devices, making the method reproducible for future applications of its use. This utilisation of patients own devices was also intentional, with many recognised advantages for future use in trials and routine practice, as reported in current literature [163,119]. It reduces costs, for example, as the supply of devices to patients is not required. It also reduces learning burden, as patients can use a device they are already familiar with. The resources associated with app development, training in use of the app and the need for ongoing management of the app are also avoided. These benefits make the method more feasible for use in studies with large sample sizes or in routine practice where resources are limited. Indeed, the 'Bring your own device' (BYOD) approach has been a practical model for collecting data in clinical trials [119]. This PhD work has produced generic, reproducible instructions for patients to take standardised wound images that are not specific to a mobile phone app or a particular device, which can now be used in future applications of the method with required modifications if needed (for example, to accommodate any specific requirements for photographing wounds in different locations on the body).

There have been several recent advances in methods for collecting electronic patient-generated data for aiding SSI diagnosis over the past 12 months. An ongoing randomised trial in the UK, for example, is exploring whether a

smartphone-delivered tool can facilitate the assessment of SSI and result in earlier treatment [171]. The study aims to recruit 500 patients undergoing emergency abdominal surgery. The wound assessment tool is based on the CDC diagnostic criteria and ASEPSIS grading scale, being the most commonly used at the time of designing the study. Items for patients to complete were written based on the criteria from these existing scales. Unlike the current study, however, the items were not developed using robust methodology and have not been validated. Patients are also required to submit a wound image via the tool, which utilises the same IT software (REDCap) used in this PhD work. Instructions for patients on how to take a standardised image of their wound, however, are lacking.

Technology and the use of wound images for aiding SSI diagnosis continues to advance. There are now, for example, cameras available that can detect temperature using infrared, making it possible to obtain thermographic profiles of wounds to contribute to SSI diagnosis [172,173]. There are types of thermal imaging cameras also now available on the market for use with smartphones. Whilst these techniques undoubtably contribute and are useful for diagnosing SSI where temperature of the wound is a sign of infection, it will be some time before this technology is readily available on patients' own devices in the general population.

6.4. Strengths and limitations

Reflections on study methodology and the specific strengths and limitations of the individual studies have been described previously, in the Discussion section at the end of each results chapter (Chapters 3 and 5). This is to facilitate coherence of the work for the reader of this thesis. Strengths and limitations relevant to the work as a whole are now described below.

6.4.1. Strengths

Sample size, study design and multidisciplinary collaboration

Important strengths of the studies undertaken in this PhD research include the large number of patients, multiple centres and wide range of different types of surgery (including elective and unplanned) within the specialty under study that were involved. This supports the validation and generalisability of the work, increasing its relevance to the wider population. Undoubtably, a further strength of this PhD work has been the involvement of a collaborative multidisciplinary team. The studies have been designed and conducted with input from patients, nurses, surgeons, microbiologists, health service researchers, health economists, statisticians and medical illustrators to inform the design, conduct and analysis. The involvement of the multidisciplinary team has ensured that both the new outcome measure and the method for obtaining patient-generated wound images are relevant to a wide range of stakeholders in wound care and SSI measurement. Great strength comes from the involvement of patients and the public to ensure that

the work has meaning and relevance to those that will benefit from it. Likewise, the involvement of surgical trainees who are the next generation of healthcare providers that will be using the research outputs also add strength to this work. For example, several requests to use the new outcome measure have come from surgical trainees planning studies and writing funding applications for research fellowships that will contribute to the impact and future research beyond this PhD.

Having the engagement, support and opportunity to work with a multidisciplinary team to do the research has been extremely valuable and powerful for dissemination and implementation of the work. It has, for example, provided opportunities for wider dissemination of the work via research networks and in social media than may have otherwise been possible. This has promoted implementation of the new outcome measure and method for patients to take and transmit images in other studies and increased the impact of the work. Specific RCTs already using the new outcome measure include:

1) the NIHR HTA funded ROSSINI 2 trial: Reduction of Surgical Site Infection Using Several Novel Interventions; a multicentre, multi-arm, multi-stage (MAMS) trial with 6610 participants (grant number 16/31/123).
2) the NIHR RfPB funded SUNRRISE trial: Single Use Negative pRessure dressing for Reduction In Surgical site infection following Emergency laparotomy; an RCT with 630 participants (grant number PB-PG-0416-20045).

3) the NIHR HTA funded SWHSI-2 trial: Surgical Wounds Healing by Secondary Intention; an RCT with 696 participants. This study has also recently incorporated patient-generated images of wounds for remote assessment (grant number 17/42/94).

4) the NIHR DRF programme funded DEFeND trial: Determining the Effectiveness of Fibrin Sealants in Reducing Complications in Patients Undergoing Lateral Neck Dissection: A randomised external pilot trial; aiming to recruit 50 patients.

6.4.2. Limitations

Study population

Although the large number of patients involved in the two studies described in this thesis is a considerable strength of this work, it is important to acknowledge limitations. The work was undertaken within the two surgical specialties of abdominal and vascular surgery. These surgical specialities have a higher risk of SSI [27], making them particularly relevant for developing and evaluating new methods to improve SSI outcome assessment. Whilst it was considered justified to focus the research within specific surgical specialties for practical, clinical and logistical reasons, it is acknowledged that generalisation of the findings to other wound specialities may be limited as a result. The suitability of the measure for measuring SSI in other specialities such as, for example, orthopaedics, is unknown. Similarly, the suitability of the photography method for patients undergoing other types of surgery where, for example, wounds are in different locations on the body, is unknown. Plans to validate the outcome measure in study populations

undergoing different types of surgery are underway and are described in more detail later in this chapter (section 6.7).

There are other limitations of this work in relation to the study population. It is important to acknowledge that the findings from these studies are potentially subject to participation or volunteer bias. This type of bias refers to potential underlying differences between patients that volunteer to participate in research and those that do not [174]. People that did not accept the invitation to participate in the current studies may have had, for example, different demographics or clinical profiles. This can have implications for interpretation of the study findings and ultimately their generalisability to the wider population [175]. Similarly, generalisability is also limited by the population demographic and socio-economic characteristics of those that did participate in the studies. There is, for example, very little ethnic variation in the study populations. It is also acknowledged that data on participants' socio-demographics for the complete sample is lacking, including information on education, and this is a limitation for understanding the generalisability of the findings to a broader population.

Interpretation of the study findings are further limited by potential underlying differences between the participants that responded in the studies and those that did not. This type of bias is known as non-response bias [176]. With relevance to the current studies, this has implications, for example, in the analysis of criterion validity of the new outcome measure. The ability of the SSI measure to discriminate between SSI and no SSI in the current dataset was demonstrated to be high. The analysis, however, was based on available

data from those participants that completed and returned the self-reported SSI measure and attended a face-to-face follow-up for a reference SSI assessment. It is unknown whether the sensitivity and specificity of the measure to discriminate between SSI and no SSI would be different if data from all participants were available for analysis. Those that did not respond may have, for example, fewer or more wound healing problems. It was known that a higher number of participants who did not complete the SSI measure in the validation study had unplanned surgery. Based on evidence that SSI rates are higher in patients undergoing unplanned surgery [17], it could be suggested, therefore, that participants that responded to the study may have had more wound problems and higher rates of SSI than those that did respond. Certainly, this is an area that warrants further investigation.

The potential for bias in the study population is also relevant to the development and evaluation of the method for taking and transmitting wound images. It is recognised that findings of patients' acceptability of the method to take and transmit images of the wound after leaving hospital, for example, may be biased in the sample of participants accepting the invitation to participate in the study. It is unknown whether acceptability of the method would be similar for participants that declined the invitation to take part in the study. Patients who may have found the experience of seeing their wound upsetting and therefore not willing to photograph it, for example, may have declined the invitation to take part. Similarly, the interpretation of the findings from the photography study is also subject to non-response bias. For example, usability and acceptability of the method in participants that were recruited to the study but did not take and transmit wound images, and were

unable to be contacted to elicit reasons, is unknown. Further testing to explore this is warranted.

Literature searches

An updated systematic search of the literature to identify SSI assessment tools was not undertaken as part of this thesis. As described in the discussion section of this study at the end of Chapter 3, the likely impact of this for identification of new SSI tools was regarded to be minimal because the tools identified in the previous systematic review conducted by Bruce et al. 2001 [31] were found to still be the most commonly used tools in current practice. A content analysis of these tools, combined with data from the interviews, allowed for a comprehensive set of domains to be identified to inform the content of the new outcome measure.

An informal scoping search was conducted to identify relevant documents to inform the development of instructions for patients to take wound images. The lack of a formal search for guidance on taking wound photography instructions is a potential weakness of this study as it may have identified existing literature on this topic that was missed in the scoping search. As previously described in the methods chapter for this study (Chapter 4) the impact of not conducting a formal search was, however, considered minimal. This is because guidelines for professional medical illustrators on how to take wound images were used as a key source document for informing the patient instructions. It was considered that this document was comprehensive to include all the relevant components for taking a clear, standardised image of

the wound and as such, along with the other included source documents, was sufficient to serve as a basis for developing the instructions for patients. This was then subsequently iterated and improved with input from patients during cognitive interviews in the next phase of the study.

Response rates

It is important to acknowledge the response rates in the two studies and how these impact on the interpretation of the findings. The response rate for the participant-completed outcome measure achieved through postal administration was 561/792 (70.8%) (Study 1). The response rate for obtaining wound images from patients achieved through electronic transmission was 46/89 (51.7%) (Study 2). Whilst these response rates are acceptable and in line with published literature from other similar studies using postal questionnaires or electronic patient-reported data capture (for example, a systematic review of strategies to improve response rates in healthcare studies reported an average response rate to postal questionnaires of 65% and studies that have used ePRO systems to capture electronic data from patients have reported completion rates of 47% to 51% [177-179]), they are, however, a limitation to the generalisability and interpretation of the study findings. It is recognised that efforts to improve response rates would need to be considered for applications of the method in future research and routine practice to achieve more complete data to ensure they are accurate and reliable. Response rates would need to be improved if the methods were being used, for example, to measure a primary outcome in a trial. Ideas to address this are returned to later in this chapter under the sub-heading 'Considerations for future applications of the work'.

6.5. Applicability of the work to research and routine practice in wider contexts

Whilst the outcome measure and method for obtaining patient-generated images were developed and evaluated in the context of a research study, a strength of this work is its relevance to both research and clinical practice in a wider context. Many of the findings are transferrable to other settings, emphasising the relevance and importance to examine the applicability of the methods in further work.

6.5.1. Applications in routine surgical follow-up, SSI surveillance and audit

Applications of the work in contexts other than research include monitoring of wounds in routine practice. For example, use of the outcome measure and images could be used in routine patient care as tools to inform further treatment or intervention. The role of patient-reported data integrated into routine care as a screening tool or to provide tailored advice to patients has many potential benefits for patients and healthcare providers, as demonstrated in the field of oncology [180]. An example of how the outcome measure is already being considered in this context is to monitor patients after routine surgical follow-up. A research group based at the Medical University of South Carolina, US, are developing a mobile phone app intended for use by patients for routine SSI follow-up after surgery [181]. The group have requested permission to include the items from the new outcome measure

within the app to collect data and monitor the wound for signs of infection. The study aims to recruit the first cohort of patients in Spring 2020.

The outcome measure and patient-provided images also have applications for use in SSI surveillance and audit. There is potential for the methods to provide more accurate and reliable data on the number of SSIs that have occurred after the patient has left hospital. The founder and lead for the GIRFT programme (described previously in section 6.3), for example, recognises the limitations of their SSI audit. In a published commentary shortly after the publication of the development work from this PhD research, the programme lead supported the use of the outcome measure to improve the methodology for identifying SSI, writing that "methods to improve SSI identification, such as those proposed by Macefield et al. (2017) are very much welcomed."[24]. The PHE SSISS team are also aware that this new outcome measure has been developed and validated following an invited talk given by the author of this thesis at the Healthcare Infection Society 2018 conference and subsequent networking with members of the PHE team. Incorporation of the new outcome measure could add significant value to existing PHE surveillance methodology which currently uses an unvalidated questionnaire [34]. Opportunities to collaborate with the PHE team will be explored as part of the author's plans beyond this PhD work.

It is recognised that several aspects of the outcome measure and method for patients to take and transmit images would need modifications for use in routine surgical follow-up, surveillance and audit. Transmission of images, for example, would need to be compatible with NHS IT systems and firewalls

so that linkage with patients' electronic health records are possible. Integration of patient-reported data with electronic health records, for example, requires careful planning, with consideration of ethical and legal issues [182]. Further work is warranted to explore potential barriers and how they may be overcome in the pathway to uptake and implementation of the methods in these settings.

6.5.2. Applications in other surgical specialties

The development and evaluation of the new outcome measure and method for obtaining patient-generated wound images was performed within the context of abdominal and vascular surgery. SSIs can, however, occur after any type of surgery making these new methods applicable to SSI outcome assessment in other surgical specialties outside those in which they have been developed. Examples of studies in other specialties that are already using the outcome measure include head and neck cancer, ulcerated skin cancer and cardiothoracic surgery. The new measure and photography method also have applications to wounds healing with secondary intention, that is, wounds that have not been closed after an operation and are instead left 'open' to heal from the bottom up. An example of how this is already being explored is in the SWHSI-2 trial [183,184]. The research team have included the outcome measure in the currently recruiting RCT and validation of the measure in this context will be examined. The author of this thesis is a member of the study management group for this trial. Although the new outcome measure and photography method have applications for use in these other surgical specialties and other types of wounds, it is recognised that modifications and further work would be required to evaluate their use in patients undergoing

these different procedures. More detail on further validation in other populations is discussed below (section 6.7 'Future research').

It is recognised that applications of the photography method in other surgical specialties would need to consider the feasibility of the method in relation to the location of the wound. In the current study, a few participants reported problems with taking images because of the location of the wound on the body made it difficult to see the camera screen to check that the wound was correctly framed in the image. Similar problems have been reported in the literature. For example, a study with nine patients following vascular and general surgery explored the usability of an app that allowed patients take images of their wound [83]. Problems with photographing groin wounds were reported because it was difficult to achieve the optimal angle to take the photograph. In the current study, the issue of dignity was raised if the wound was in a personal location on the body and how participants may not want others to help take an image. Further issues with wound location emerged from findings in the current study. Some of the reasons that assessors judged the wound images as insufficient related to the where the wound was on the body. There was a need to manipulate the skin in order to see the wound in full, for example, wounds inside the belly button. Whilst the current study identified that there are some wounds that may still require a face-to-face assessment so the healthcare professional can manipulate the skin to get a full view of the wound, it is likely the methods developed in this thesis are applicable for assessing most types of wounds. Further work and validation, considering all these potential issues regarding wound location, would need

to be considered in future applications of the method outside of general and vascular surgery.

6.5.3. Applications in wound care outside of surgery

The outcome measure and method for patient to take and transmit images have applications for use in other fields of wound care outside of surgery. In other types of wounds such as pressure ulcers, leg ulcers and diabetic foot ulcers, for example, wound healing and infection are important outcomes [185-187]. It is recognised that applications of the methods may require some modifications for use with these other types of wounds. Some items in the outcome measure, such as the item asking about dressing use, for example, may need adapting to make it applicable to chronic wounds that require dressings for longer periods of time. It may also be necessary to modify the photography instructions for use to assess other types of wounds. For example, it may be necessary to ask patients to photograph their wounds from different angles if perception of wound depth is important. Any modifications to the outcome measure and photography instructions would subsequently require further validation to ensure they are fit for purpose.

6.5.4. Applications in low- and middle-income countries (LMICs)

A major strength of this work is its potential application worldwide. Whilst the work to develop and validated the SSI measure and the collection of images was performed within the UK, the methods have great potential for use in low- and middle-income countries (LMICs) where SSI rates are higher and access to hospitals is often limited due to distance or financial constraints [188]. Methods for remote wound assessment, therefore, have potential benefits to the patient and the health services in LMICs. Work to evaluate the feasibility and validity of the outcome measure in low resource settings has recently been funded as a sub-study within the NIHR-funded FALCON trial: Pragmatic multicentre FActorial randomised controlled triaL testing measures to reduCe surgical site infection in lOw and middle income couNtries (grant number 16/136/79). An NIHR doctoral fellowship (awarded to James Glasbey at the NIHR Unit on Global Surgery at the University of Birmingham) embedded within the NIHR HTA-funded FALCON study will explore the feasibility and diagnostic accuracy of the measure administrated by telephone for assessment of SSI following abdominal surgery in low and middle-income countries. Validity of the tool for use as a telephone-based assessment will be examine compared to an in-person face-to-face assessment. The author of this thesis will work closely with this group and has been invited to be a member of the study steering group. It is recognised that use of the methods in LMICs would require linguistic and cultural translations and this is planned as part of the fellowship. International validation of the methods is discussion in more detail later (section 6.7).

6.5.5. Considerations for future applications of the work

In addition to any modifications and further validation required for application of this work to other contexts described above, there are other considerations for future applications of this work.

Ideas to maximise response rates have been considered. An electronic version of the outcome measure, for example, could be developed and participants could be asked for their preference on whether they would prefer a postal or electronic version of the questionnaire. This is often done in research studies to maximise response [189]. Validation of the outcome measure for electronic patient self-report would first be needed to assess its suitability and this is discussed later in this chapter (section 6.7). Other ideas to improve response rates could consider alternative ways to remind participants to respond. In the current studies, reminders were typically made by telephone calls. Some difficulties in reaching participants by telephone, however, were often found with many participants not answering calls. The study researchers were telephoning from hospital or university landlines where the number was often 'protected' and the caller ID is not displayed on the receiving mobile phone. The issue of no caller ID is recognised in the literature as a problem for trying to contact participants [190]. It was considered as a potential contributor to not being able to reach participants in the current studies. Alternative methods to remind participants in future studies could consider using text messages (which may also have cost-saving advantages) as well as

emails or calling from landlines with recognised numbers with an aim to maximise response rates.

Further considerations for future applications of the method to obtain patient-generated digital images include the use of patients' own devices to take and transmit images. Whilst the use of patients' own devices is an emerging field in SSI research and routine practice with many potential benefits for the patient and health services (as described in Chapter 1), some disadvantages, however, are also recognised. Not all patients have access to an appropriate device, for example. This may be problematic if the method were being used to collect outcome data in trials, as it introduces selection bias because the sample is not representative of the population [175]. It may be problematic in routine care, as it disadvantages patients without access to the appropriate device. Other problems include potential costs incurred to patients when there is a need to have internet access to transmit images. Privacy and security issues with using patients own devices may also be an issue and are important considerations for future applications of the methods [73].

6.6. Dissemination of the work

The previous paragraphs describe the applicability of the work to research and routine practice in wider contexts. In order for uptake and implementation of the new outcome measure and method for obtaining patient-generated images in these settings, effective and efficient dissemination of the work is key. Informing the surgical field and other healthcare professionals involved in wound assessment that this research has been done has been an important part of this PhD work. Work has already been disseminated in several ways. In summary, this has included:

i) Four peer-reviewed publications. Papers report: 1) the development work and 2) the validation work for the new outcome measure; 3) the novel approach to outcome measure design and the development of a measure for completion by patients and/or professionals and 4) the published NIHR HTA monograph as part of the wider Bluebelle feasibility study [147,148,50,1].

   Details of these publications are provided at the beginning of this thesis. A fifth paper reporting the development and evaluation of the method for obtaining patient-generated wound images is planned.

ii) Four oral conference contributions at national and international conferences in the UK and US: the International Clinical Trials Methodology Conference (2015 and 2019), the Society for Clinical Trials Conference (2018) and the Infection Prevention Society conference (2015).

iii) Four conference poster presentations at national and international conferences in the UK and US: International Clinical Trials Methodology Conference (2017), Patient Reported Outcome Measures conference (2018 and 2019) and the Society for Clinical Trials Conference (2019).

iv) Five invited talks at conferences: the Wound Research Network Scientific meeting (2016, 2017 and 2019), the Healthcare Infection Society International Conference (2018) and the European Wound Management Association Wound Care conference (2020).

During the course of this PhD, the author has become involved in several wound-related research networks and working groups as mentioned earlier in this chapter. These include WReN and the NHS England NWCSP [170,25]. The author was invited to join the NWCSP as a committee member of the surgical wounds workstream. The NWCSP was set up in 2018 with the purpose to develop a national strategy that focuses on improving wound care relating to pressure ulcers, lower limb ulcers and surgical wounds. The surgical wounds workstream are developing a set of recommendations to improve care for patients with surgical wounds. This includes recommendations to improve accurate diagnosis of SSI and the use of images for post-operative monitoring, to which the methods developed in this PhD are key. Involvement in these groups, therefore, has provided an ideal platform for dissemination of the research to those who may use them in practice. Continued involvement in the groups will allow for further dissemination to encourage uptake of the new methods going forward.

Public Engagement

Public engagement has also been conducted as part of this PhD work. The author of this thesis successfully applied to take part in the University of Bristol Research without Borders Festival, May 2018. This was a one-day public engagement event at the Colston Hall, open to the public, industry and other professionals and academics. A stand displayed the Selfi wound study and the opportunity for people to try taking self-taken images of 'fake wounds' (temporary tattoos) with their own mobile device. Discussions with people who visited the stand, feedback and observation of attempts to take photographs provided valuable input prior to the testing-phase of the study.

Summary for participants

The work has also been disseminated to study participants. A visual abstract, for example, to summarise the findings from the Selfi wound study was designed and sent to all study participants via email in December 2019. The initial draft of the visual abstract was reviewed by two members of a PPI panel working with the NIHR Bristol Biomedical Research Centre (BRC) for feedback and suggestions for improvements to ensure that it was appropriate and easy to understand for the general public.

Webpage

Further efforts to make the work available to the wider scientific community have included the development of a dedicated webpage for the new outcome measure. The webpage is hosted within the Centre for Surgical Research

webpages on the University of Bristol website [191]. A summary describing the new measure and how it was developed and validated is included, with links to the publications for readers to have access to full details. The webpage includes a purpose-designed request form for anyone wanting to use the measure, asking completers for to provide details on reasons for using the measure, including purpose (e.g. trial or other research study), details of intended use (e.g. setting, number of patients), requests for translations as well as contact details. The webpage also includes a licence for non-commercial users to use the measure (with no fee for non-commercial use), which has been drawn up in collaboration with the University of Bristol Research and Enterprise Development team. The webpage hosts the licence agreement, the registration form and a sample copy of the outcome measure.

6.7. Future research

Areas for further work

1) Further validation in different patient populations

As discussed earlier in this chapter, further validation of the outcome measure and photography method is required to examine their application in different patient populations. Testing with patients, for example, with different demographics, different types of wounds and undergoing other types of surgery is required to determine how useful the methods are in patient populations other than that of the current study. Plans to work with others to further validate the new outcome measure are already underway. As described earlier (section 6.3), seven grant applications from other UK academics and clinicians have been funded for studies that include the new outcome measure. Recruitment and collection of data in four of these studies has started. These studies (four RCTs and three cohort studies) will allow for further examination of the performance of the new outcome measure in these different populations. Agreements to share data and work with these groups to further validate the outcome measure have been made.

2) Determining a threshold score for SSI

A key next step for further work is to establish an SSI 'threshold' score for the outcome measure. This would mean setting a cut-off threshold, for which scores over that particular value would be indicative that the patient had an SSI. Such as threshold score is important for future applications of the measure for research or audit purposes that require the number of SSIs in a

patient population to be reported. A threshold score may be useful, for example, in clinical practice as a screening tool to trigger further clinical investigation or treatment. Patient self-reported questionnaires with established threshold scores are used in other fields, for example, for detecting and guiding treatment decisions for depression [192].

Choice of an appropriate threshold score is a clinical question and has to balance the risk (that is, the cost and consequences) of over or under estimating SSI. This may depend on the purpose of its use. For example, it may be preferable to have a lower threshold score for SSI if the measure was being used as a screening tool for inviting patients for a face-to-face follow-up to inform whether treatment is needed. It may be better to be more over-cautious and have a higher rate of 'false-positives' than to risk missing some cases of SSI if the threshold score was too high. The 'seriousness' of an undetected SSI in clinical practice compared to an undetected SSI in trial outcome data may be more significant because it may have direct negative consequences if it results in a patient not being treated.

Determination of a threshold score requires analysis of sensitivity and specificity of the outcome measure compared with a reference SSI diagnosis [112]. Data from the current study suggested a cut-off score around 6 to 8 appeared to be a reasonable threshold for suggesting SSI / no SSI with relatively few misclassifications compared to a face-to-face diagnosis using the CDC criteria. More work with data from other studies is needed to explore this further.

There are plans after this PhD research to work with others to establish the SSI threshold score. The studies described above that are already collecting data using the new outcome measure are also designed to include a face-to-face assessment of the wound and an SSI diagnosis using the CDC criteria. This is the same reference assessment to that used in the current study. These data will allow further exploration of the ability of the outcome measure to discriminate between SSI and no SSI in these different datasets and explore an SSI threshold.

3) Combined use of the outcome measure and images

An important area for further work is to combine the use of the outcome measure and patient-generated digital images. It is anticipated that combined use of the outcome measure and images will have added value for SSI assessment. Images may, for example, help to determine a diagnosis of SSI in a 'grey area' range of scores around a potential threshold for SSI. In the data in the current study a cut-off score of 6 to 8 appeared to be a reasonable threshold for suggesting SSI / no SSI compared to the reference face-to-face SSI diagnosis. Further work could explore the use of images for assessing wounds in this group where assessment of SSI using the new outcome measure alone is uncertain. A study that collects data using the new outcome measure, with or without a patient-generated wound image would be valuable to examine accuracy of SSI diagnosis using these new methods. Possible study designs include an RCT randomising patients to complete the new outcome measure after leaving hospital and return it with or without transmitting a supplementary digital image of their wound. Surgeons' accuracy and confidence in making an SSI diagnosis could be compared.

4) Full evaluation of the method for remote wound assessment using patient-generated digital images

This PhD work performed an evaluation of the method for obtaining patient-generated wound images, for potential use for SSI assessment in a research or clinical context. This next step for this work is conduct a full evaluation of the method. A pilot study, using the method to collect images from patients after having surgery and using the images to assess the wound for SSI in a research study or in routine follow-up is warranted. Evaluation of the clinical benefits of the method could then be examined, including measures of patient/healthcare professional satisfaction to see if the methods meet the user's needs and expectations. Satisfaction is a recommended outcome to assess in full evaluations of methods that involve electronic data collection and human-system interaction [130].

5) Electronic use of the SSI measure for digital delivery

Another area for further work that would add value to the outcome measure is it's reproduction for electronic data capture, known as 'eMigration' or development as an electronic patient-reported outcome measure (ePROM) [125,119]. The outcome measure was developed and validated for use as a paper questionnaire. As mentioned earlier in this chapter, administration of electronic outcome measures has many benefits over paper-based methods, including convenience and cheaper and faster data collection with fewer data entry errors [193,194]. Migration to an ePROM would need to be done using robust methodology [145]. Consistent formatting, font size, ease of navigation and specific instructions for electronic completion, for example, would all

need to be considered. Tests of usability to ensure that respondents are able to complete the ePROM correctly would also need to be conducted.

6) International validation: cross-cultural and linguistic translation

An important area for future work is international validation of the new outcome measure. All the participants contributing to this work were recruited in the UK. The validation of the outcome measure involved a multi-centre study that recruited participants from different regions including Bristol, Birmingham and Worcester with the aim of having diversity in the population. Recruitment aimed to include a broad sample of demographics as possible. Despite this, there was very little ethnic diversity in the study population and the majority of the participants in the studies were white.

The involvement of participants from outside the UK would have added cultural and ethnic diversity to the study population that may have potentially influenced the findings. For example, it may have influenced the language used in items in the new outcome measure. An international study, however, would have added administrative complexity and language and cost implications outside the resources possible for this PhD. As a result of its UK focus, there are cultural limitations to this work. It is currently unknown how the outcome measure would perform in a more diverse population, for example, whether the wording and plain language descriptions are appropriate. The language used to describe symptoms, for example, may be less understood in different cultures. Similarly, the suitability of the photography method in different cultural and ethnic groups in unknown.

Cross-cultural translations and further testing in populations from different cultures and different ethnic groups is therefore warranted.

The SSI outcome measure could be translated for populations in different cultures and countries to allow international implementation and use of the outcome measure with non-English speakers. Guidance and established methodology for translating outcome measures exist to ensure this process is done robustly [48]. This involves a two-stage process including forward and backward translations to ensure the translation is accurate and appropriate. As described earlier, specific interest is the application of the methods developed in this PhD work to low- and middle-income countries where rates of SSI are higher than the UK. There are plans to work with others to explore this. The recently funded NIHR DRF described earlier (applicant James Glasbey) plans to undertake work to examine cross-cultural translation of the measure in an English-speaking South African population as part of the wider NIHR-HTA funded FALCON study (grant number 16/136/79).

7) Real-time monitoring of wound healing

A further area of work is to investigate the applicability of the methods developed in this PhD for real-time monitoring of wound healing. The timeframe for collecting data in the current studies was approximately 30 days after surgery, a widely accepted timeframe for SSI to have occurred [32]. Real-time monitoring of wounds using the methods at more immediate timepoints sooner after surgery may have advantages for identifying signs and symptoms of SSI earlier. It may mean, for example, treatment can be initiated earlier before signs and symptoms worsen. Similarly, use of the

methods to get a clinical opinion when patients have concerns about their wound healing may help to reduce patient anxiety.

Future management, licensing and marketing of the outcome measure

In collaboration with the University of Bristol Research and Enterprise Development team, a recent agreement with an external company to manage licensing and future requests to use the new outcome measure has been set up to encourage the adoption and recognition of the new outcome measure. This decision has been a result of the high number of requests to use the new outcome measure over the last 12 months, including commercial interest (for example, from a company developing a new bacteriostatic dressing interested in using the outcome measure in an early-phase observational study). Oxford University Innovation (www.innovation.ox.ac.uk) have a Clinical Outcomes team that provide academic and consultancy services to support the management, licensing and marketing of clinical and patient-reported outcome measures. Their existing portfolio includes 30 outcome measures developed within Oxford University and other institutions. They will manage administration and future requests for use of the SSI outcome measure, with the official name as the Bluebelle Wound Healing Questionnaire (WHQ), including licensing responsibilities and fees for commercial requests and will develop the marketing and support structure. The company will advertise the measure using its own marketing channels, for example, their website, newsletter and Oxford University press releases. The potential impact through marketing through this professional company is a very exciting prospect for the future of the SSI outcome measure and the work conduct within this PhD.

6.8. Conclusion

Accurate and reliable SSI outcome assessment is critical for routine surgical practice, research and audit. Challenges in SSI assessment, especially after the patient has left hospital, have been problematic for researchers and clinicians. This means SSI data are unreliable and true rates of SSI are unknown. This work has addressed a gap in the field of SSI assessment. Before the research for this thesis, no outcome measure for SSI existed. A new outcome measure, for patient or healthcare professional completion, has now been developed for use in hospital or after the patient been discharged. The measure has been developed with input from key stakeholders. Patients and healthcare professionals participated in qualitative interviews to inform the development of the measure, ensuring that the content was comprehensive and included issues that were important to patients and well as healthcare professionals for SSI assessment. A novel approach in formulating items for the questionnaire was applied by using plain language alongside medical terminology. This was found to maximise content validity of the measure and ensure that items were interpreted as intended. The measure was pre-tested with both patients and healthcare professionals to ensure it was acceptable and fit for purpose. The new outcome measure has been shown to be comprehensive and easy to complete. Findings from the validation study demonstrated the measure to be reliable and valid for assessing SSI in closed primary surgical wounds.

This PhD work has made a second contribution to the field of SSI assessment, utilising the advances in technology and move towards using digital images for remote assessment. A reproducible method for obtaining patient-generated digital images of wounds from patients after leaving hospital has

been developed and evaluated for its potential use in future research and clinical practice. The method utilises patients own mobile devices and has shown to be feasible, acceptable to patients and capable of providing images of sufficient quality for remote wound assessment. This innovative patient-centred method, incorporating digital images and data transmission, combined with the new outcome measure, has considerable potential for improving SSI assessment after hospital discharge.

Plans for future work are now directed towards further evaluation and implementation of these new methods in research studies and routine practice to improve SSI outcome assessment in future. Several areas for further work have already commenced, involving multidisciplinary research teams across the UK. The high level of interest in using the new outcome measure is very encouraging. The potential for the new methods to have significant impact presents an exciting prospect for the use of these methods in future. The methods developed in this PhD work provide novel contributions to the field of surgery and SSI outcome assessment, and ultimately provide value for future SSI research, routine follow-up and audit.

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APPENDICES

Appendix 1. Publication reporting the SSI measure development work

Journal of Infection Prevention

Original Article

Development of a single, practical measure of surgical site infection (SSI) for patient report or observer completion

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Abstract

Background: Surgical site infections (SSIs) are the third most common hospital-associated infection and can lead to significant patient morbidity and healthcare costs. Identification of SSIs is key to surveillance and research but reliable assessment is challenging, particularly after hospital discharge when most SSIs present. Existing SSI measurement tools have limitations and their suitability for post-discharge surveillance is uncertain.

Aims: This study aimed to develop a single measure to identify SSI after hospital discharge, suitable for patient or observer completion.

Methods: A three-phase mixed methods study was undertaken: Phase 1, an analysis of existing tools and semi-structured interviews with patients and professionals to establish the content of the measure; Phase 2, development of questionnaire items suitable for patients and professionals; Phase 3, pre-testing the single measure to assess acceptability and understanding to both stakeholder groups. Interviews and pre-testing took place over 12 months in 2014–2015 with patients and professionals from five specialties recruited from two UK hospital Trusts.

Findings: Analyses of existing tools and interviews identified 19 important domains for assessing SSIs. Domains were developed into provisional questionnaire items. Pre-testing and iterative revision resulted in a final version with 16 items that were understood and easily completed by patients and observers (healthcare professionals).

Conclusion: A single patient and observer measure for post-discharge SSI assessment has been developed. Further testing of the validity, reliability and accuracy of the measure is underway.

Keywords

Outcome measure, post-discharge wound assessment, questionnaire development, surgical site infection (SSI), surgical wound, surveillance, wound healing

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Introduction

Surgical site infection (SSI) is the third most common healthcare-associated infection (HCAI) to occur after surgery (Smyth et al., 2008). Occurrence is associated with multiple factors, including patient co-morbidity, wound site, degree of contamination and whether surgery is performed in the elective or emergency setting. Incidence may be as great as 40% (Anthony et al., 2011), being highest in unplanned procedures involving the gastrointestinal tract (Pinkney et al., 2013; Public Health England, 2014). SSI leads to significant morbidity (Whitehouse et al., 2002) and is the most common reason for unplanned readmission to hospital (Merkow et al., 2015). At worst, SSIs can even result in death (Coello et al., 2005). Ultimately, they can have major cost implications for health services (Jenks et al., 2014). Reduction of SSI is therefore of high priority to patients and to health services, and in the UK rates are routinely monitored for audit purposes in most National Health Service (NHS) Trusts. Consequently, it is essential that SSIs are accurately identified and measured for effective clinical governance and for research evaluating interventions to minimise SSI.

Commonly used tools to identify SSI include the Centres for Disease Control and Prevention (CDC) criteria and the ASEPSIS grading scale (Horan et al., 1992; Wilson et al., 1986). These tools, however, were developed primarily for use in-hospital, in circumstances when most patients had post-operative hospital stays of several days. Experienced staff are required to complete the tools, yet they do not identify SSIs consistently (Gibbons et al., 2011; Wilson et al., 2004). Problems with quantifying accurate incidence arise because many infections take time to develop and over 70% of SSIs may occur after the patient is discharged from hospital (National Institute for Health and Clinical Excellence, 2013; Petherick et al., 2006; Wilson et al., 2013). This proportion is likely to increase as surgical techniques become less invasive and hospital stays get shorter. Post-discharge assessment of SSI by healthcare professionals is possible but relies on extensive resources and is expensive, requiring additional appointments to review the wounds (Tanner et al., 2009). One solution to improving post-discharge assessment is to use patient reported outcome measures, i.e. tools completed by patients themselves. Indeed, patient-reported modifications of the CDC criteria and ASEPSIS scale have been developed and are in use (Public Health England, 2013; Wilson et al., 2013), yet these questionnaires were based on clinical and microbiological perspectives and were designed to capture similar information as in-hospital assessment. They have lacked patient input and have not been formally validated (Petherick et al., 2006). There is, therefore, a need to address these issues and design a measure for SSI that is appropriate for use after patients have been discharged from hospital. A suitably developed and validated tool for patient completion is needed, as well as a post-discharge assessment tool for healthcare professional use. However, the use of separate tools (i.e. for patient and observer completion) to assess the same outcome may introduce the risk of a different underlying construct being measured. A single measure that could be used by both patients and observers would ensure that the content validity is the same regardless of who is completing it. Such a measure may have potential applications in routine surveillance, research and clinical audit (Gibbons et al., 2011).

The aim of this study, therefore, was to develop a reliable single measure for SSI that can be used after the patient has been discharged from hospital and can be completed by the patient themselves and/or an observer.

Methods

Study design

This was a mixed methods study conducted in three phases using an existing framework for developing patient-centred outcome measures (Sprangers et al., 1993). Phases included: Phase 1, an analysis of existing tools and interviews with patients and professionals to establish the content of the measure; Phase 2, developing questionnaire items and designing an optimal tool; and Phase 3, cognitive interviews to pre-test the tool. Subsequent psychometric and diagnostic accuracy testing of the new measure will be described elsewhere.

Ethical approval was obtained from the NHS Health Research Authority NRES Committee London – Camden & Kings Cross (14/LO/0640). Written informed consent was obtained from all patients and professional participants.

Phase 1: establishing the content of the measure

Analysis of existing tools. A detailed analysis of the most commonly used tools (definitions and grading scales) for SSI assessment, identified by a previous systematic review (Bruce et al., 2001), was undertaken. The purpose was to ascertain relevant signs, symptoms and criteria for defining SSI to include in the new measure. Tools studied were the Public Health England (PHE) clinical criteria for SSI (based on the CDC criteria) and surgical wound healing post-discharge questionnaire for patients (Public Health England, 2013), and the ASEPSIS grading scale (Wilson et al., 1986) and associated post-discharge patient questionnaire (Gibbons et al., 2011; Wilson et al., 1990). Individual criteria or questionnaire items and their response categories were extracted and recorded verbatim. Criteria and items were grouped into SSI 'domains' based on the sign, symptom or intervention to manage infection. Grouping was performed by four authors (BCR, JMB, AN and RM) using methods for categorising health domains described previously (Macefield et al., 2014).

Interviews with patients and professionals. Semi-structured interviews with patients with experience of SSI (n = 9) and professionals involved in post-surgical care (n = 10) were conducted to explore SSI signs, symptoms and interventions for managing them, and to identify new domains not covered by the existing tools. Views on the existing PHE and ASPESIS tools were collected by asking participants to complete them during interviews and asking their opinion on their suitability, relevance and ease of completion. Predesigned interview topic guides were used to cover these objectives. Interviews were conducted by one researcher (AN), were audio-recorded and transcribed in full. Details on participant sampling are provided below.

Phase 2: designing the measure: 'operationalisation' of domains and item development

Findings from Phase 1 were used to design a provisional new measure. Each of the SSI domains were operationalised into a questionnaire item according to standard processes (Sprangers et al., 1993). Items were initially worded in lay language. Where the underlying domain could be described with a medical term, this word was included at the end of the item in parentheses. Medical terms were selected from existing tools or by the study team.

The single measure was designed as a questionnaire with two grammatical variations; one using the first-person context, i.e. 'your wound', appropriate for patient use, and another using the third-person context, i.e. referring to 'the wound', to be appropriate for observer completion.

Phase 3: pre-testing the measure

The provisional new measure was pre-tested in cognitive interviews. Patient participants (n = 28) who had undergone surgery were purposefully sampled (see below). Professional participants (n = 14) were recruited from primary care and secondary/tertiary care teams involved in surgical wound care. Patients were asked to complete the measure in relation to their own wound. Professionals were asked to use an example of a recent patient or a hypothetical case. Cognitive interviews assessed face validity, comprehension, suitability and acceptability. Interviews were conducted face-to-face with a researcher (RM or TM) at participants' homes or places of work.

Participants were observed and asked to 'think aloud' while completing the questionnaire. Interviewers used probes to explore items further, such as "What does that word mean to you?" or "What do you interpret that word to mean?" (Beatty and Willis, 2007). Patients' and professionals' views on the inclusion of the medical terms used at the end of the items were explored. Participants were specifically asked about their understanding and perception of the medical description to ensure that the lay wording was an accurate and appropriate interpretation. Interviews were audio-recorded and summarised in descriptive memoranda.

Participants and sampling

Eligible patients had undergone abdominal general surgery or caesarean section from two participating UK hospital Trusts. Patients were identified and approached by research nurses and surgical trainees (NB, RB and DM) while in hospital. Phase 1 sampling was restricted to patients with confirmed or suspected SSI, identified before discharge or on readmission to hospital. Phase 3 sampling included patients who had undergone surgery within the previous 30 days. Patient details were communication to other members of the study team (AN, RM or TM) to contact and arrange subsequent interviews. Healthcare professionals involved in post-surgical care from the participating hospitals were approached directly by members of the study team (AN and RM).

Participants were purposively sampled to include a range of sociodemographic characteristics and types of surgery, and a range of clinical staff and expertise. Sampling and analysis for pre-testing the measure (Phase 3) was carried out as an iterative process until no new themes emerged.

Data analyses

Phase 1: A descriptive table was used to map original items from the source documents (existing clinical tools and patient questionnaires) to the identified SSI domains (Table 1). Interview data were analysed using an inductive approach. Data were coded and grouped into similar themes (thematic content analysis) (Braun and Clarke, 2006). A descriptive account of the common identified themes was generated, including signs and symptoms of wound infection, follow-up care and treatment required, commonalities across specialties and feedback on the current measures of SSI. The account concluded with a summary of points to consider when developing the new measure.

Phase 3: Descriptive memoranda from the cognitive interviews included key findings or problems and suggestions for modifications and improvements to the provisional measure; changes to items, response categories, formatting, instruction and layout. Obvious issues or repeated suggestions were considered by the study team and edits were made in a new version of the measure. Data were analysed iteratively so that items could be modified, added or deleted to reflect emerging findings and allow further exploration of modifications in subsequent interviews.

At regular intervals throughout Phases 1–3, findings and versions of the measure were circulated to the immediate study team for comment and suggestions, and to the wider study team and collaborators before a large study meeting during Phase 2.

Table 1. Identified SSI domains and mapping of criteria and items from existing tools.

SSI domain	Criteria / Item from existing measure	Source (existing tool)
Wound healing	Have all of these wounds healed without any problem at all?	ASEPSIS PQ
	Have you had any problems with the healing of your wound?	PHE PQ
Wound heat	The area around the wound felt warmer/hotter than the surrounding skin	PHE PQ
	Heat	PHE CDS
Wound redness	Has the wound been red?	ASEPSIS PQ
	Redness or inflammation spreading from the edges of the wound	PHE PQ
	Erythema	ASEPSIS CDS
	Redness	PHE CDS
Wound discharge	Has the wound discharged clear yellow fluid?	ASEPSIS PQ
	Has the wound discharged pus?	ASEPSIS PQ
	Purulent drainage	PHE CDS
	Was there any discharge or leakage of fluid from any part of the wound? If yes, was it either Clear or blood stained? Yellow/green (pus)? Other? - please specify	PHE PQ
	Serous discharge/serous exudate	ASEPSIS CDS
	Purulent exudate	ASEPSIS CDS
Layers separating - spontaneous	Has the wound broken open?	ASEPSIS PQ
	The edges of any part of the wound separated or gaped open	PHE PQ
	Separation of deep tissues	ASEPSIS CDS
	Incision spontaneously dehisces [or opened by surgeon]	PHE CDS
Wound swelling	The area around the wound became swollen	PHE PQ
	Localised swelling	PHE CDS
Wound pain	Pain or soreness in addition to the discomfort experienced following the operation	PHE PQ
	Localised pain and tenderness	PHE CDS
Fever	Fever (temperature 38°C or more)	PHE CDS
Contact with healthcare professional	If you saw a healthcare worker because of these symptoms, please indicate who you saw from the list (GP/district nurse/midwife/doctor or nurse at the hospital/other – please specify)	PHE PQ
Dressing needed	Has a district nurse had to dress the wound?	ASEPSIS PQ
Antibiotics needed	Have you been given antibiotics for wound infection?	ASEPSIS PQ
	Have you been prescribed antibiotics for an infection in the wound? If yes, who prescribed them?_____	PHE PQ
	Antibiotics prescribed	ASEPSIS CDS
	Antibiotics prescribed by GP for SSI (patient reported only)	PHE CDS
Layers separating - deliberate	Incision opened by surgeon [or spontaneously dehisces]	PHE CDS
Hospital admission	Have you been admitted to hospital elsewhere?	ASEPSIS PQ
	Have you been readmitted to hospital with an infection of the surgical wound? To the hospital at which the operation was carried out? To another hospital?	PHE PQ
Drainage needed	Drainage of pus under local anaesthesia (including vac therapy)	ASEPSIS CDS
	Purulent drainage	PHE CDS

(Continued)

Table 1. (Continued)

SSI domain	Criteria / Item from existing measure	Source (existing tool)
Wound cleaning	Has the wound been opened and cleaned under general anaesthetic in hospital?	ASEPSIS PQ
	Debridement of wound (general anaesthesia)	ASEPSIS CDS
	Purulent drainage	PHE CDS
Abscess	Has a doctor opened/drained an abscess?	ASEPSIS PQ
	Abscess or other evidence of infection found during a re-operation, by radiology or histopathology examination	PHE CDS
Microbiology	Did any healthcare worker take a sample from your wound to send to the laboratory?	PHE PQ
	Aspirated fluid/swab of surgical site yields organisms and pus cells are present	PHE CDS
	Isolation of bacteria	ASEPSIS CDS
	SSI causative micro-organisms	PHE CDS
Prolonged hospital stay	Stay as inpatient prolonged over 14 days	ASEPSIS CDS
Smell	–	–

CDS, clinical data sheet; GP, general practitioner; PHE, Public Health England; PQ, patient questionnaire; SSI, surgical site infection.

Results

Phase 1: establishing the content of the measure

Analysis of existing tools. A list of 42 items was generated from the PHE criteria, ASEPSIS grading scale and associated patient questionnaires. These were categorised and grouped to 18 domains; eight measuring SSI signs and symptoms and ten measuring wound management interventions (Table 1).

Interviews with patients and professionals. Participant demographics for the Phase 1 interviews are shown in Table 2. Patients (n = 9) had confirmed or suspected SSI after a range of gastrointestinal (GI) surgeries and professionals (n = 10) had various roles from GI, obstetric and paediatric specialties.

Interview data supported findings from the analysis of the existing measures. The following signs and symptoms were described as being indicative of infection: cellulitis or redness around the wound; discharge of pus; tenderness, pain or soreness of the wound; breakdown/opening of the wound; feeling generally unwell (often associated with a temperature or fever) and occasionally tachycardia (in two interviews with staff member in obstetrics); hot wound; abscess; swelling; and raised white blood cell count. The first three signs and symptoms were mentioned more frequently, without further questioning or prompting. Wound management care and interventions included: prescription of antibiotics; wound drainage; dressing changes; cleaning of wound; taking swabs/blood/imaging investigations; observation; consulting colleagues. It was possible to map interview data to the 18 domains identified in the existing tools. In addition, however, interview data identified 'smell' as a domain not currently measured in existing SSI tools. This was described by both patients and professionals.

Analysis of the existing tools and interviews therefore resulted in a total of 19 domains identified domains to consider for inclusion in the new measure (Table 1).

Views on the current SSI tools and issues to consider for the new measure included simplification and use of lay language, reducing the subjectivity of items and the need to distinguish varying SSI severity in the response categories. Confusion and misunderstanding emerged with some words used in existing tools including discharge, pus, abscess and antibiotics. There was a common tendency to talk about wound healing rather than wound infection. Filter questions often gave rise to responses that were contradictory. For example, some participants responded that they had no problems with the healing of their wound (in answer to a filter question on one measure) yet responded that they had experienced some of the symptoms when asked to complete the rest of the measure.

Phase 2: designing the measure

A provisional new measure was designed based on the identified domains and findings from Phase 1. 'Microbiology' and 'Prolonged hospital stay' were excluded domains as they were considered to be inappropriate for a measure completed by a patient or observer after discharge and because such information is more suitably obtained from hospital records.

Table 2. Phase I participants: establishing the content of the measure.

		Professionals (n = 10)	Patients (n = 9)
Gender	Female	6	4
	Male	4	5
Role	Consultant	5	
	Midwife	1	
	Nurse	1	
	Registrar	3	
Specialty	Obstetrics	4	
	Paediatrics	3	
	Stoma care	1	
	Upper GI	2	
Type of surgery	Upper GI benign		2
	Upper GI cancer		1
	Lower GI benign		3
	Lower GI cancer		1
	Appendicectomy		2
Wound infection	Confirmed		2
	Suspected		1
	Absent		2
	Missing data		4

GI, gastrointestinal; GP, general practitioner.

Phase 3: pre-testing the measure

Interviewees were patients (n = 28) and healthcare professionals (n = 14) with a range of sociodemographics and expertise (Table 3). The mean time since patients' surgery was 46 days (range, 6–208 days). Interviews lasted on average 27 min (range, 13–52 min).

Participants' views on including medical terms alongside lay language in a single measure were divergent. For example, some professionals raised concerns about including medical terms in a questionnaire intended for patients because of the potential for generating worry or confusion, or that patients might be prompted to look up words on the Internet and see distressing images of serious cases. Generally, however, patients reported that the inclusion of medical terms in parentheses was acceptable with the majority paying attention only to the lay wording. Two patients reported that they might look up the medical term on the internet out of curiosity.

During pre-testing, interviews highlighted that the initial lay language description for some items had oversimplified the intended domain; the oversimplification only became apparent because a medical term had been included in parentheses. For example, the item intended to assess debridement of the wound (i.e. the medical removal of dead, damaged or infected tissue) was initially phrased 'Has your wound been cleaned out? (debridement)'. However, pre-testing found that different responses were given from participants who read the lay language compared to those who read and understood the medical term. Some participants responded 'yes' to this item if the wound had been washed with saline solution or 'superficially' cleaned, whereas others responded 'yes' only if dead or damaged tissue had been removed from the wound. Therefore, this item was modified to 'Has your wound been scraped or cut to remove any unwanted tissue? (debridement)'. Interviews also identified items where the medical term as well as the lay description needed revising to accurately measure the intended domain. For example, the item initially phrased 'Have the edges of any part of the wound separated? (dehiscence)' was revised to 'Have the edges of any part of the wound separated on their own accord? (spontaneous dehiscence)' to distinguish it from interventions where the wound was opened up intentionally by a doctor or nurse. These examples demonstrate that the inclusion of medical terms alongside lay language was beneficial during the development of the measure because it served as a grounding for the intended underlying construct.

The measure was modified throughout the pre-testing phase and eight versions were tested in subsequent interviews. Modifications included changes to the wording and structure of items, formatting, instructions and response categories. The final version consisted of 16 items, with nine including medical terms (Figure 1). Items relate to: (1) patient-reported signs or symptoms potentially indicative of SSI; and (2) patient-established information of wound care management and clinical interventions for treating SSI.

Discussion

This study developed a single measure for SSI assessment that can be completed after a patient has been discharged from hospital. It has been shown to be comprehensive, easy to complete and suitable for use by patients and observers (in this example, healthcare professionals). It is advantageous for establishing information about SSI signs, symptoms and clinical interventions, irrespective of where the patient has received care during the SSI follow-up period. Describing items in lay language and with medical terminology was found to reduce the risk of misinterpretation and ensured that the intended underlying domains were measured. The measure will now undergo full psychometric testing and assessment of diagnostic accuracy to determine its suitability for use in trials or post-discharge surveillance studies.

Existing commonly used measures for SSI are based on long-standing tools developed over 20 years ago. They were primarily designed for clinical use and did not include patients' views during development; their adaptations as

Table 3. Phase 3 participants: pre-testing the measure.

		Professionals (n = 14)	Patients (n = 28)
Gender	Female	10	11
	Male	4	17
Age at time of interview (years)	21–30	0	1
	31–40	7	2
	41–50	3	2
	51–60	3	6
	>60	1	17
Role	Midwife	3	–
	Hospital/Research nurse	3	–
	Practice/Community nurse	1	–
	Surgical trainee	4	–
	GP	3	–
Specialty	General practice/community	4	–
	Obstetrics	3	–
	Upper/Lower GI surgery	6	–
	Intensive care	1	–
Length of time qualified	<10	1	–
	10-20	7	–
	>20	6	–
Time since surgery (weeks)	<1	–	1
	1–2	–	2
	2–4	–	9
	>4	–	16
Type of surgery	Upper GI	–	9
	Lower GI	–	10
	Caesarean	–	3
	Hernia repair	–	6

patient reported questionnaires were done with little reported validity and reliability testing (Petherick et al., 2006). The new measure has been developed using thorough methodology and followed an established framework for the development of outcome measures (Sprangers et al., 1993). Mixed methods, including an examination of existing tools and interviews with patients and professionals, were used to inform the content of the measure and pre-test its acceptability. The current "dual-completion" (patient and observer) measure is a novel approach to outcome assessment, which traditionally employs multiple tools that have been developed separately and are used separately by patients and professionals. There are, however, some limitations to this study. First, interviews were conducted with patients and professionals from a small number of surgical specialties where rates of SSI are known to be higher than others. Generalisation to other surgical categories is limited and we do not know how the questionnaire will perform in a wider population. The suitability of the measure for assessing SSI in other specialities, for example, orthopaedics, is unknown. Further work is required to validate the usefulness of the measure in a larger sample and wider population. Second, observers in the context of this study referred to healthcare professionals and completion by other observers (for example, carers) was not tested. The measure also has cultural limitations, and further testing of the wording and lay language descriptions in a more diverse population may be warranted. Third, the measure has been developed for use as a postal questionnaire. An electronic adaptation that could implement filter questions and be completed and returned as an online survey might have advantages for minimising the amount of missing data.

Figure 1. Final version of the SSI measure after pre-testing.

	Since you left hospital after having surgery....	**Response categories**
1	Was there redness spreading away from the wound? (erythema/cellulitis)	Not at all / A little / Quite a bit / A lot
2	Was the area around the wound warmer than the surrounding skin?	Not at all / A little / Quite a bit / A lot
3	Was any part of the wound leaking fluid?	Not at all / A little / Quite a bit / A lot
	a) Was it clear fluid? (serous exudate)	Not at all / A little / Quite a bit / A lot
	b) Was it blood-stained fluid? (haemoserous exudate)	Not at all / A little / Quite a bit / A lot
	c) Was it thick and yellow/green fluid (pus/purulent exudate)	Not at all / A little / Quite a bit / A lot
	d) I do not know	
4	Have the edges of any part of the wound separated/gaped open on their own accord? (spontaneous dehiscence)	Not at all / A little / Quite a bit / A lot
	a) Did the skin separate?	Not at all / A little / Quite a bit / A lot
	b) Did the deeper tissue separate?	Not at all / A little / Quite a bit / A lot
	c) I do not know	
5	Has the area around the wound become swollen?	Not at all / A little / Quite a bit / A lot
6	Has the wound been smelly?	Not at all / A little / Quite a bit / A lot
7	Has the wound been painful to touch?	Not at all / A little / Quite a bit / A lot
8	Have you had, or felt like you have had, a raised temperature or fever? (fever <38°C)	Not at all / A little / Quite a bit / A lot
9	Have you sought advice because of a problem with your wound, other than at a routine planned follow-up appointment?	Yes / No
	If yes, please tell us who you sought advice from:	
	a) A doctor or nurse at the GP surgery/medical centre/walk-in centre	Yes / No
	b) A doctor or nurse at the hospital	Yes / No
	c) A midwife or health visitor	Yes / No
	d) Another health advisor	Yes / No
	Please describe who the other health advisor was _____	
10	Has anything been put on the skin to cover the wound? (dressing)	Yes / No
	If yes,	
	a) Was this done by a doctor or nurse at the GP surgery/ medical centre/walk-in centre?	Yes / No
	b) Was this done by a nurse/midwife/health visitor at home?	Yes / No
	c) Was this done by you/your partner/friend/family member?	Yes / No
	d) Was this done by a doctor/nurse/midwife at the hospital?	Yes / No
	e) Please describe what was put on to cover the wound _____	
11	Have you been back into hospital for treatment with a problem with your wound?	Yes / No
12	Have you been given antibiotics for a problem with you wound?	Yes / No / Don't know
	If yes,	
	a) Were the antibiotics given as tablets/liquid?	Yes / No / Don't know
	b) Were the antibiotics given via drip?	Yes / No / Don't know
	If you know the name of the antibiotic(s) you have taken, please write it here _____	
13	Have the edges of your wound been deliberately separated by a doctor or nurse?	Yes / No / Don't know
14	Has your wound been scraped or cut to remove any unwanted tissue? (debridement of wound)	Yes / No / Don't know
15	Has you wound been drained? (drainage of pus/abscess)	Yes / No / Don't know
16	Have you had an operation under general anaesthetic for treatment of a problem with your wound?	Yes / No / Don't know

Footnote: The version shown is for patient completion (with items written in first-person context).

Finally, the measure has been designed for use after hospital discharge. If the measure is used during the initial hospital stay some of the items are redundant (e.g. 'Have you been back into hospital for treatment of a problem with your wound?').

The measure is currently being tested for validity and reliability in a larger sample of patients (approximately 400) undergoing abdominal surgery. How the responses from a completed questionnaire may be used to diagnose the presence/absence or type of SSI will be investigated in the analysis of the validation study and findings will be reported separately. Following validation and diagnostic accuracy testing, the suitability of the measure for collecting SSI outcome data for research and routine surveillance can be evaluated. Future research using the new measure is intended in randomised controlled trials of interventions to reduce SSI.

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Contributors

Members of the Bluebelle Study Group contributed to the study design and read the final version of this manuscript. Other author roles are as follows: Kerry Avery provided qualitative expertise and supervised the conduct and analysis of the interviews and commented on the final draft of the manuscript. Richard Bamford recruited patients for the SSI development interviews and commented on the final draft of the manuscript. Jane Blazeby supervised the overall study, contributed to the analysis of the existing SSI measures and interviews, contributed to the design of the SSI measure, provided surgical and methodological expertise throughout the study, commented and edited all versions of the manuscript. Natalie Blencowe recruited patients for the SSI development interviews, contributed to design of the SSI measure, commented on earlier and final drafts of the manuscript. Melanie Calvert contributed to design of the SSI measure, commented on earlier and final drafts of the manuscript. Rhiannon Macefield led and coordinated the SSI measure study, conducted the analysis of existing SSI tools, conducted and analysed interviews, designed and revised the SSI measure, wrote the first draft of this paper, all subsequent revisions and collated other author contributions to produce the final draft of the manuscript. David Messenger recruited patients for the SSI development interviews and commented on earlier and final drafts of the manuscript. Thomas Milne contributed to the design of the SSI measure, conducted and analysed interviews and commented on earlier and final drafts of the manuscript. Alex Nicholson conducted and analysed interviews and commented on earlier and final drafts of the manuscript. Thomas Pinkney provided surgical expertise, commented on earlier and final drafts of the manuscript. Barnaby Reeves provided clinical and methodological expertise throughout the study including contributions to the design of the SSI measure and commented on earlier and final drafts of the manuscript.

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Appendix 2. Publication reporting the SSI measure validation work

Original article

Validation of the Bluebelle Wound Healing Questionnaire for assessment of surgical-site infection in closed primary wounds after hospital discharge

Bluebelle Study Group*

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Background: Accurate assessment of surgical-site infection (SSI) is crucial for surveillance and research. Self-reporting patient measures are needed because current SSI tools are limited for assessing patients after leaving hospital. The Bluebelle Wound Healing Questionnaire (WHQ) was developed for patient or observer completion; this study tested its acceptability, scale structure, reliability and validity in patients with closed primary wounds after abdominal surgery.

Methods: Patients completed the WHQ (self-assessment) within 30 days after leaving hospital and returned it by post. Healthcare professionals completed the WHQ (observer assessment) by telephone or face-to-face. Questionnaire response rates and patient acceptability were assessed. Factor analysis and Cronbach's α examined scale structure and internal consistency. Test–retest and self- *versus* observer reliability assessments were performed. Sensitivity and specificity for SSI discrimination against a face-to-face reference diagnosis (using Centers for Disease Control and Prevention criteria) were examined.

Results: Some 561 of 792 self-assessments (70·8 per cent) and 597 of 791 observer assessments (75·5 per cent) were completed, with few missing data or problems reported. Data supported a single-scale structure with strong internal consistency (α greater than 0·8). Reliability between test–retest and self- *versus* observer assessments was good (κ 0·6 or above for the majority of items). Sensitivity and specificity for SSI discrimination was high (area under the receiver operating characteristic (ROC) curve 0·91).

Conclusion: The Bluebelle WHQ is acceptable, reliable and valid with a single-scale structure for post-discharge patient or observer assessment of SSI in closed primary wounds.

*Members of the Bluebelle Study Group are co-authors of this study and can be found under the heading Collaborators

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Introduction

Surgical-site infection (SSI) is the third most common healthcare-associated infection in the UK[1] influencing patient outcomes, quality of life and healthcare resources[2]. Rates of SSI vary considerably, depending on the type of surgery performed (for instance, clean or contaminated) and individual patient risk factors. Many SSIs take time to become apparent, often developing or becoming symptomatic after the patient has left hospital[3,4]. Rate estimates are influenced by methods and timing of data collection, particularly the robustness of postdischarge follow-up[2,5,6]. Accurate assessment after discharge is therefore key to SSI surveillance and research is needed to minimize this important healthcare issue[7].

Assessing wounds for SSI after hospital discharge can be done by patient self-reporting, by asking patients to return for an outpatient appointment, or by conducting home visits. The latter two methods are resource-intensive[8]. Patient self-reporting can reduce these burdens, although accurate tools are needed. Existing postdischarge self-reporting questionnaires for patients[9–11] have methodological weaknesses. They have been adapted from tools intended for completion by a professional, lack patient input in their development, have not been validated

for use in a postdischarge setting, and have been criticized because they do not account for symptom severity – an important aspect in SSI diagnosis[12]. The Bluebelle Wound Healing Questionnaire (WHQ) was developed with input from patients and multidisciplinary healthcare professionals to address these limitations. It assesses signs, symptoms and wound care interventions relevant for the diagnosis of SSI in closed primary wounds, specifically after the patient has left hospital[13]. Early work[13] has demonstrated that the WHQ is comprehensive, easily understood, and can be completed by patients and/or observers (healthcare professionals). The present study examined the acceptability, scale structure, reliability and validity of the WHQ in a large sample of patients undergoing surgery with closed primary abdominal wounds.

Methods

The Bluebelle Wound Healing Questionnaire

The WHQ was developed as part of the Bluebelle study[14], a feasibility study that included a pilot RCT to examine whether an RCT of different wound dressing strategies for reducing SSI was possible[14,15]. Initial development of the WHQ has been reported previously[13]. The WHQ was designed as a single questionnaire for patient and/or observer completion.

The version of the questionnaire undergoing validation in this study consisted of 16 items: eight relating to signs and symptoms of SSI, and eight relating to wound care interventions. Two of these items included additional components, collecting more detail on signs and symptoms, if applicable. Early versions of the questionnaire also included questions on resource use (for the wider Bluebelle feasibility study) that were not relevant to the diagnosis of SSI, and therefore are not included in these analyses.

Response categories for sign and symptom items were: 'not at all' (score 0), 'a little' (1), 'quite a bit' (2) and 'a lot' (3). Response categories for wound care intervention items were: 'yes' (score 1), 'no' (0) and 'don't know'. Higher scores, therefore, indicated more problems.

Study design

Two data sets from the Bluebelle study were used in this analysis: data from a cohort recruited specifically to validate this new measure; and data from the pilot RCT. Research ethical approval was granted from the National Health Service (NHS) Health Research Authority National Research Ethics Service (NRES) Committee London – Camden and Kings Cross (reference 14/LO/0640) and the South West – Frenchay Research Ethics Committee (reference 15/SW/0008).

Eligible participants were aged over 16 years, undergoing elective or unplanned abdominal general surgery or caesarean section. Participants who lacked capacity, ability to read or understand English, and prisoners were excluded. Further inclusion and exclusion criteria were relevant to the wider requirements of the Bluebelle study and have been reported previously[14]. Studies ran between August 2015 and January 2016, and between March 2016 and November 2016 (cohort study and pilot RCT respectively) from four UK NHS hospital trusts. Participants were recruited by research nurses, surgical trainees or other trained members of the study team on hospital wards before or after surgery. Potential participants were given an information leaflet, and were provided with sufficient time to consider involvement and discuss the study before being approached again to take part. All participants were asked to give written informed consent.

Data collection

Fig. 1 illustrates the study design and data collection.

Wound Healing Questionnaire self-assessment

The WHQ was distributed by post for participants to complete and return (by stamped addressed envelope, included) 30 days after surgery. Instructions were to complete the WHQ in relation to events since hospital discharge. A subset of 50 cohort participants (sampled during 1 month of the study) were posted an additional WHQ within 1 week of completing the first WHQ (for test–retest assessment). In a series of debriefing questions included with the WHQ, data were collected from the cohort participants on the time needed for WHQ completion, whether help was required, and whether items were confusing or difficult to answer. Reminders for non-responders were sent only to participants of the pilot RCT.

Wound Healing Questionnaire observer assessment

In the cohort study, the WHQ was completed by a clinical member of the study team via a telephone call with participants 4–5 weeks after surgery. In the pilot RCT, the WHQ was completed by a clinical member of the study team during the participant's face-to-face follow-up appointment between 4 and 8 weeks after surgery.

Reference diagnoses of whether SSI had occurred since the time of surgery were made in face-to-face study follow-up appointments between 4 and 8 weeks after the operation using Centers for Disease Control and Prevention (CDC) criteria and classification of no SSI, superficial,

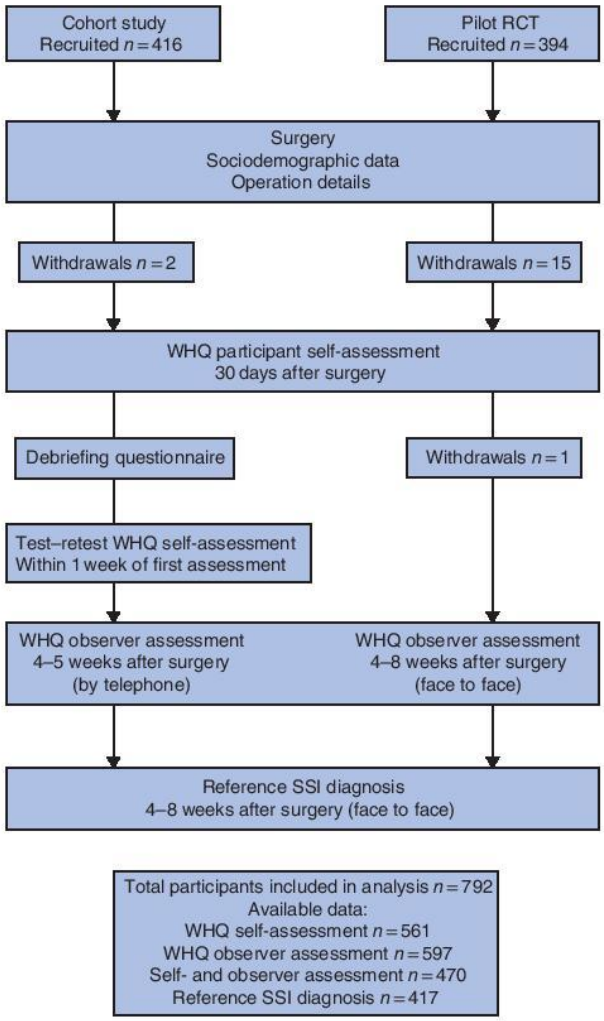

Fig. 1 Participants and data contributing to validation of the Wound Healing Questionnaire. WHQ, Wound Healing Questionnaire; SSI, surgical-site infection

deep or organ/space[16]. Diagnoses were made by an independent member of the study team, blinded to the WHQ self- and observer assessment, using any available sources of information from the participant and hospital records. All pilot RCT participants and a convenience sample of cohort participants (sampled by availability due to limited study resources) underwent a face-to-face reference wound assessment.

Analyses

All 16 items were included in the initial analysis. Missing responses to the items with multiple components (collecting more detail on signs and symptoms, if applicable) were imputed with values of zero if no response was expected (for example, if the sign or symptom had not occurred). Summation of item scores was performed as suggested by the data. Reference SSI diagnoses were dichotomized to create a binary variable with 0 = no SSI and 1 = SSI of any type (combining CDC classifications of superficial, deep and organ/space SSI due to low numbers of reported deep and organ/space SSI).

Acceptability

Acceptability of the WHQ was explored in three ways: first, by examining response rates (the proportion of completed WHQ self- and observer assessments); second, by exploring missing responses to individual items (indicating possible issues such as not understanding the item); and third, by examining answers to the debriefing questions.

Scale structure

Exploratory factor analyses examined the underlying structure and constructs of the questionnaire. Analyses were conducted separately for self- and observer data. First, all iterations of item pairs were explored using Pearson's correlation coefficients. Pairs with very high correlations ($r = 0{\cdot}9$ or above) were examined for similarity and considered for redundancy and exclusion before conducting factor analyses[17]. Next, three separate factor analysis models were run, specifying the maximum number of factors to be retained as one, two and three factors (maximum-likelihood method of estimation). Models were initially explored with data from the cohort study, and the best-fitting model was applied to data from the pilot RCT as a method of independent validation of the scale structure. The best-fitting model was applied finally to the combined cohort and pilot RCT data. A sensitivity factor analysis was performed using a polychoric matrix because of the ordinal, categorical nature of the WHQ data[18]. Multitrait scaling analyses were also applied as a comparative statistical approach[19].

Internal consistency (internal reliability) of the scales identified from the factor analyses was examined using Cronbach's α coefficient[17]. Values greater than 0·7 were considered to have good internal consistency[17].

Reliability

Test–retest reliability[20] was assessed by comparing self-assessment responses to the WHQ completed twice over a period of anticipated stable health. Stable health was assumed if responders reported that they had not been back into hospital for treatment with a problem with the wound (item 11) in the retest assessment. Cross-tabulations of responses and weighted κ statistics were calculated.

Equal weights between response categories for ordinal items (items 1–8) were assumed, with weighted values of 0, 0·333, 0·667 and 1 between categories. κ values below 0·4 were considered to indicate poor agreement. Values between 0·4 and 0·75 were considered to indicate fair to good agreement[17].

Inter-rater reliability (agreement between self- and observer assessments, where data from both assessments were available) was explored, to examine the reliability of the self-assessment for collecting outcome data in a future large-scale trial. Cross-tabulations of item responses and weighted κ statistics were calculated as described above. Percentages of agreement and discordance were examined.

Validity

Criterion validity was examined against the reference SSI diagnosis to demonstrate how well the WHQ performed in discriminating between individuals with and those without SSI. Cross-tabulations of the reference CDC diagnosis ('no SSI' or 'SSI of any type') and a binary variable of the self-assessment WHQ total score (created by a cut-off score; for instance, a WHQ total score of less than or equal to x) were compared. Sensitivity and 1 – specificity values of the WHQ for different cut-off scores were used to plot a receiver operating characteristic (ROC) curve, representing the trade-off between sensitivity and specificity[21].

The overall ability of the WHQ to discriminate between individuals with and those without SSI was measured by the area under the ROC curve (AUC) and 95 per cent confidence intervals. An AUC value approaching 1·0 was interpreted to indicate good discrimination with high sensitivity and specificity, whereas a value of 0·5 was interpreted as the measure not being able to discriminate at all[21].

Analyses were performed using STATA® statistical software version 14 (StataCorp, College Station, Texas, USA).

Modifications for the final questionnaire

Findings from the above were used to inform modifications to the final version of the WHQ, considering rates of missing data for individual items, answers to the debriefing questions and overlap between items (if correlations of r greater than 0·9 were observed).

Results

Data for 792 participants were examined (*Fig. 1*). *Table 1* presents participant sociodemographic, clinical and operative details. Median times from surgery to participant self- and observer WHQ assessments were 29 (i.q.r. 24–33) and 37 (32–48) days respectively.

Table 1 Baseline sociodemographic, clinical and operative details of the study sample

	No. of patients* (n = 792)
Age (years)†	53·2(17·5)
No. of men	364 (46·0)
Duration of surgery (h)	
< 1	213 (28·3)
1–2	182 (24·2)
2–3	139 (18·5)
> 3	218 (29·0)
Missing	40
Type of operation	
Caesarean section	95 (12·2)
Oesophagogastric resection/gastrectomy	17 (2·2)
Pancreatobiliary resection	38 (4·9)
Antireflux surgery	12 (1·5)
Bariatric surgery	6 (0·8)
Cholecystectomy	102 (13·1)
Colectomy/hemicolectomy	95 (12·2)
Hartmann procedure/reversal	21 (2·7)
Rectal/anterior resection	72 (9·2)
Stoma formation alone	11 (1·4)
Stoma closure/reversal alone	19 (2·4)
Small bowel resection	38 (4·9)
Groin hernia repair	61 (7·8)
Abdominal wall hernia repair	37 (4·7)
Appendicectomy	57 (7·3)
Diagnostic laparoscopy/laparotomy	31 (4·0)
Adhesiolysis	12 (1·5)
Other	56 (7·2)
Missing	12
Type of surgery	
Elective	606 (81·3)
Unplanned	139 (18·7)
Missing	47
Risk factor	
Smoker	
Current	114 (14·7)
Ex-smoker < 1 month	236 (30·4)
No	426 (54·9)
Missing	16
Diabetes, any type (n = 775)	60 (7·7)
ASA grade	
I	232 (31·7)
II	373 (51·0)
III	118 (16·1)
IV	8 (1·1)
Missing	61
BMI (kg/m^2)† (n = 762)	28·0(6·1)

*With percentages as proportions of available data (excluding missing values) in parentheses unless indicated otherwise; †values are mean(s.d.).

Acceptability

Response rates

Self- and observer WHQ assessments were completed for 561 of 792 (70·8 per cent) and 597 of 791 (75·5 per cent) participants respectively, with 470 of 791 (59·4 per cent) of these participants having both sets of data completed. In total, 104 of 792 participants (13·1 per cent) did not have any WHQ self- or observer assessments available (complete non-responders).

Missing responses to items

Less than 3 per cent of responses were missing for most items (10 of 16) in the self-assessments and no items had more than 4 per cent of responses missing (*Table S1*, supporting information). For observer assessments, nearly all items (15 of 16) had less than 2 per cent of responses missing. Missing responses to the additional components of the two items for which further information on signs and symptoms was intended to be collected (if applicable) were, however, high, with up to 43 per cent of self-assessments missing a response when one would have been expected. Missing responses to these additional components were lower in the observer assessments, although levels were still notable and ranged between 8 and 17 per cent (*Table S1*, supporting information).

Responses to debriefing questions

Most participants (276 of 302, 91·4 per cent) reported that the questionnaire took fewer than 10 min to complete. Less than 6 per cent reported needing help or finding items difficult or confusing to answer.

Scale structure

A high correlation ($r = 0{\cdot}95$) was observed between item 4 ('Have the edges of any part of the wound separated/gaped open of their own accord? (spontaneous dehiscence)') and its additional component collecting further information: 4a ('Did the skin separate?'). Study team agreement of similarity in the underlying concept of these questions deemed item 4a to be redundant, and it was therefore excluded from factor analyses.

Factor analyses of the cohort and pilot RCT data separately supported a single-scale structure. Results from the combined data set are shown in *Table 2*. Item factor loadings ranged between 0·32 and 0·87 in data from participant self-assessments, and between 0·33 and 0·85 in data from observer assessments (with the exception of one item with a factor loading of 0·03). Examination of eigenvalues and factor loadings provided little evidence to suggest a better fit for a two- or three-factor model. Sensitivity analyses using a polychoric correlation matrix supported findings for a single-scale model. A comparative multitrait scaling analysis approach also demonstrated strong association of items to a single scale.

Table 2 Factor analysis: item factor loadings for a single-scale structure using combined cohort and pilot RCT data

	Self-assessment ($n = 362$)	Observer assessment ($n = 501$)
Eigenvalue	5·26	5·08
Item		
1 Was there redness spreading away from the wound? (erythema/cellulitis)	0·45	0·66
2 Was the area around the wound warmer than the surrounding skin?	0·32	0·56
3 Was any part of the wound leaking fluid?	0·87	0·85
3a Was it clear fluid? (serous exudate)	0·57	0·45
3b Was it blood-stained fluid? (haemoserous exudate)	0·72	0·58
3c Was it thick and yellow/green fluid (pus/purulent exudate)	0·57	0·64
4 Have the edges of any part of the wound separated/gaped open of their own accord? (spontaneous dehiscence)	0·66	0·63
4a Did the deeper tissue separate?	0·59	0·43
5 Has the area around the wound become swollen?	0·32	0·36
6 Has the wound been smelly?	0·49	0·43
7 Has the wound been painful to touch?	0·36	0·37
8 Have you had, or felt like you have had, a raised temperature or fever? (fever > 38 °C)	0·39	0·39
9 Have you sought advice because of a problem with your wound, other than at a routine planned follow-up appointment?	0·61	0·59
10 Has anything been put on the skin to cover the wound? (dressing)	0·42	0·54
11 Have you been back into hospital for treatment of a problem with your wound?	0·45	0·35
12 Have you been given antibiotics for a problem with your wound?	0·65	0·67
13 Have the edges of your wound been deliberately separated by a doctor or nurse?	0·41	0·40
14 Has your wound been scraped or cut to remove any unwanted tissue? (debridement of wound)	0·34	0·03
15 Has your wound been drained? (drainage of pus/abscess)	0·38	0·33
16* Have you had an operation under general anaesthetic for treatment of a problem with your wound?	–	–

*This item was dropped from the model because of collinearity.

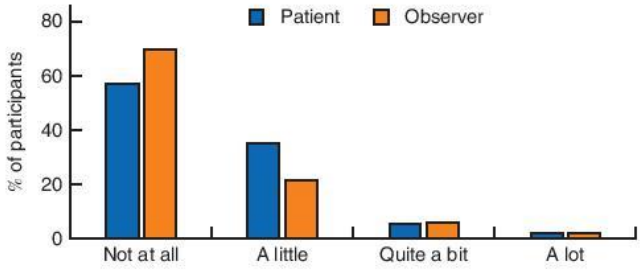

Fig. 2 Comparison of responses in self- and observer assessments. Example shows the first item in the Wound Healing Questionnaire: 'Was there redness spreading away from the wound? (erythema/cellulitis)'

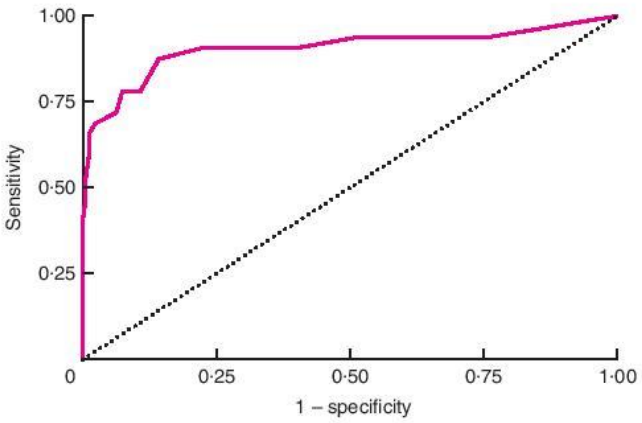

Fig. 3 Receiver operating characteristic (ROC) curve for Wound Healing Questionnaire self-assessment total score for discriminating surgical-site infection compared with reference diagnosis. Area under ROC curve = 0·91

Data suggested it was sensible to calculate a WHQ total score by summing the raw scores for each item without any weightings.

Cronbach's α for a single scale was high, with coefficients of 0·86 in participant data and 0·88 in observer data.

Reliability

Test–retest reliability

A total of 44 of 50 participants (88 per cent) included in the test–retest sample (who all reported stable health) completed and returned a second WHQ. The median time between test–retest assessments was 5 (i.q.r. 4–7) days. Agreement in responses for test–retest assessments was high, with levels of observed agreement greater than 86·2 per cent for all items (*Table S2*, supporting information). Where it was possible to calculate a reliable κ statistic, the majority of values were greater than 0·59.

Inter-rater reliability

Self- and observer assessments were available for 59·4 per cent of participants, with a median of 8 (i.q.r. 2–16) days between assessments. Agreement was generally high (observed agreement for any item greater than 84·3 per cent), although participants showed a trend to report levels of signs and symptoms to be slightly more severe than observers; an example from one item is shown in *Fig. 2* (for data from all items, see *Fig. S1*, supporting information). Where it was possible to calculate a reliable κ statistic, values were between 0·40 and 0·74 for the majority of items (*Table S3*, supporting information). Some minor discrepancy was shown between participant and observer responses to wound-care intervention items, and whether these interventions had occurred.

Validity

Reference SSI diagnoses (face-to-face, using CDC criteria) were available for 417 of 791 participants (52·7 per cent). Sensitivity and specificity values of the WHQ self-assessment for discriminating between SSI and no SSI were high, with an area under the ROC curve of 0·91 (95 per cent c.i. 0·83 to 0·98) (*Fig. 3*). Cross-tabulation of the self-assessment WHQ total score (excluding item 4a) with the reference SSI diagnosis is provided in *Table S4* (supporting information). Sensitivity and specificity values for selected WHQ cut-off scores are shown in *Table S5* (supporting information). From the present data set, a cut-off score of 6–8 appeared to be a reasonable threshold for suggesting no SSI/SSI compared with the reference diagnosis, with relatively few misclassifications.

Modifications for the final questionnaire

Evidence supported the need for minor revisions to the WHQ format to improve its efficiency and minimize missing data. Item 3 and its additional components collecting more information (3a–c) were restructured into three stand-alone items. Item 4a was removed. Items were renumbered to accommodate these changes. The response option of 'don't know' was removed. Questions collecting resource use purely for the purposes of the economic analysis of the Bluebelle pilot RCT were no longer included. The final WHQ items, after these revisions, are shown in *Table 3*.

Table 3 Revised Wound Healing Questionnaire items after analysis

Item	Response categories
1 Was there redness spreading away from the wound? (erythema/cellulitis)	Not at all / A little / Quite a bit / A lot
2 Was the area around the wound warmer than the surrounding skin?	Not at all / A little / Quite a bit / A lot
3 Has any part of the wound leaked clear fluid? (serous exudate)	Not at all / A little / Quite a bit / A lot
4 Has any part of the wound leaked blood-stained fluid? (haemoserous exudate)	Not at all / A little / Quite a bit / A lot
5 Has any part of the wound leaked thick and yellow/green fluid (pus/purulent exudate)	Not at all / A little / Quite a bit / A lot
6i Have the edges of any part of the wound separated/gaped open of their own accord? (spontaneous dehiscence)	Not at all / A little / Quite a bit / A lot
6ii Did the deeper tissue separate?	Not at all / A little / Quite a bit / A lot
7 Has the area around the wound become swollen?	Not at all / A little / Quite a bit / A lot
8 Has the wound been smelly?	Not at all / A little / Quite a bit / A lot
9 Has the wound been painful to touch?	Not at all / A little / Quite a bit / A lot
10 Have you had, or felt like you have had, a raised temperature or fever? (fever > 38 °C)	Not at all / A little / Quite a bit / A lot
11 Have you sought advice because of a problem with your wound, other than at a routine planned follow-up appointment?	Yes / No
12 Has anything been put on the skin to cover the wound? (dressing)	Yes / No
13 Have you been back into hospital for treatment of a problem with your wound?	Yes / No
14 Have you been given antibiotics for a problem with your wound?	Yes / No
15 Have the edges of your wound been deliberately separated by a doctor or nurse?	Yes / No
16 Has your wound been scraped or cut to remove any unwanted tissue? (debridement of wound)	Yes / No
17 Has your wound been drained? (drainage of pus/abscess)	Yes / No
18 Have you had an operation under general anaesthetic for treatment of a problem with your wound?	Yes / No

Discussion

This study examined the acceptability, scale structure, reliability and validity of the WHQ for use as a patient- or observer-completed tool for the assessment of SSI in closed primary surgical wounds after abdominal surgery. The WHQ was found to be acceptable to patients and demonstrated good response rates, with low levels of missing data. Analyses supported a single-scale structure to assess SSI that made clinical and practical sense. Test–retest reliability was high, and agreement between participants and observers was good. The WHQ demonstrated high sensitivity and specificity for SSI discrimination compared with a face-to-face reference CDC diagnosis. It is therefore suggested that the WHQ is an acceptable, reliable and valid patient-reported or observer-completed questionnaire for assessing SSI in closed primary surgical wounds.

Existing self-reported questionnaires for patients have been adapted mostly from the CDC criteria and ASEPSIS tools[11,16,22]. They are limited because of the lack of user involvement in development. Criticisms include that they are complicated and difficult to complete[11,23]. These self-reporting measures are also limited in their design, such as asking for yes/no responses to questions without the option to report the amount or severity of the sign/symptom. This is important when assessing a wound, as demonstrated, for example, in a recent study[12] that found the amount of exudate was more strongly associated with SSI than with the type of exudate. Existing patient measures, however, do not provide an opportunity for the amount of exudate to be captured. The same study also highlighted that bright red skin was observed in patients who had SSI, but also in patients who did not, providing another example where capturing the amount or severity of a sign/symptom rather than just its presence or absence is important. The WHQ has addressed these limitations by involving a multidisciplinary team (including patients, surgeons, nurses, microbiologists and health service researchers) in its development and by using a combination of qualitative and quantitative methods; it also underwent rigorous pretesting during development to ensure face and content validity[13]. The result is a reliable, valid, comprehensive and uncomplicated questionnaire that includes an ordinal response scale to capture symptom severity.

The study has some limitations. First, a true standard for the diagnosis of SSI without subjective perceptions or opinions is lacking, with the result that tests for criterion validity are limited. The CDC classification of SSI diagnosis was chosen as the best available reference standard for comparing the WHQ as it is the most commonly used and widely regarded tool available. Second, reports of the more major wound care interventions (such as debridement and drainage) were rare in this data set; this may have an impact, for example, on factor analyses. In addition, some discrepancy was observed between participant and observer reports of these major interventions, suggesting possible low fidelity of participant responses. Although these more major interventions were rare in this data set and the number of discordant reports between self- and observer assessments were few, this discrepancy may be

important to consider and warrants further investigation, as it may have implications for studies relying solely on patient self-assessment for collecting outcome data. Missing data in responses to the additional component parts of items collecting further information on signs and symptoms (if applicable) were relatively high, although this may be explained by the layout of the questionnaire; modifications in the revised version aim to address this. Although the wide range of abdominal operations is a strength of this study, it is recognized that the proportion of participants undergoing caesarean section (12·2 per cent) is likely to have affected the representative age of the rest of the sample presenting for general abdominal surgery and may have affected the findings. Finally, other limitations of this work relate to its testing and use after abdominal surgery alone, and for wounds healing by primary intention.

Further use and validation of the final version of the WHQ in other types of wound and surgical specialty is underway. Cut-off scores for SSI diagnosis will be explored. In addition, members of the research group are exploring the feasibility of collecting digital images of the wound taken by patients as a tool to use in conjunction with the WHQ for improving remote and blinded SSI assessment. Advances in digital technology, including the use of smart phones and other tablet devices with cameras, mean that obtaining data from patients after discharge is becoming increasing possible[24,25]. These moves towards using digital technologies to obtain patient-reported data, including images of wounds, have great potential for improving SSI assessment and ultimately patient care.

Collaborators

The study group consists of the following: Rhiannon Macefield (co-led WHQ development and validation; wrote first draft); Jane Blazeby (chief investigator, responsible for concept and design); Barnaby Reeves (study co-investigator, responsible for pilot RCT design and protocol, and WHQ validation design and analysis); Sara Brookes and Kerry Avery (advised on WHQ validation analysis); Chris Rogers (study co-investigator, responsible for overall analysis; advised on WHQ validation analysis). All of the above commented on the final draft of the manuscript.

The following authors were Bluebelle study co-investigators, with further contributions indicated: Mark Woodward (paediatrics); Nicky Welton (value for information analysis); Leila Rooshenas and Jonathan Mathers (qualitative work); Andrew Torrance; Anne Pullyblank; Robert Longman; Richard Lovegrove; Tim Draycott (study delivery); Thomas Pinkney (study delivery, contributed to WHQ development); Rachael Gooberman-Hill (patient and public involvement); Jenny Donovan (qualitative research); Joanna Coast (health economic analysis); Melanie Calvert (WHQ and other outcome measure development); Natalie Blencowe (survey of wound dressings, contributed to WHQ and other outcome measure development); Lazaros Andronis (health economic analysis).

Other Bluebelle Study Group members: Dimitrios Siassakos (study implementation); Caroline Pope, Madeleine Clout, Kate Ashton and Lucy Ellis (study set up and management); Christel McMullan (qualitative work); Rosie Harris (pilot RCT statistical analysis); Daisy Elliott (development of other study outcome measures); Jo Dumville (Cochrane update review of wound dressings). The following members (surgical trainee collaboratives) all contributed to patient recruitment and study delivery in local hospitals: Benjamin Waterhouse, Sean Strong, William Seligman, Lloyd Rickard, Samir Pathak, Anwar Owais, Jamie O'Callaghan, Stephen O'Brien, Dmitri Nepogodiev, Khaldoun Nadi, Charlotte Murkin, Tonia Munder, Tom Milne (also contributed to WHQ development), David Messenger, Matthew Mason, Morwena Marshall, Jessica Lloyd, Jeffrey Lim, Kathryn Lee, Vijay Korwar, Daniel Hughes, George Hill, Mohammed Hamdan, Hannah Gould Brown, James Glasbey, Caroline Fryer, Simon Davey, David Cotton, Benjamin Byrne, Oliver Brown, Katarzyna Bera, Joanne Bennett, Richard Bamford, Danya Bakhbakhi, Muhammad Atif, Elizabeth Armstrong, Piriyankan Ananthavarathan.

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Supporting information

Additional supporting information can be found online in the Supporting Information section at the end of the article.

Appendix 3. Methodology paper reporting the novel design of the SSI measure

BMJ Open

Development of a 'universal-reporter' outcome measure (UROM) for patient and healthcare professional completion: a mixed methods study demonstrating a novel concept for optimal questionnaire design

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ABSTRACT

Objectives To describe the novel concept of, and methods for developing, a 'universal-reporter' outcome measure (UROM); a single questionnaire for completion by patients and/or healthcare professionals (HCPs) when views on the same subject are required.

Design A mixed methods study with three phases—phase I: identification of relevant content domains from existing clinical tools, patient questionnaires and in-depth interviews with multistakeholders; phase II: item development using a novel approach that considered plain language in conjunction with medical terminology; and phase III: pretesting with multistakeholders using cognitive interviews.

Setting A case study in surgical wound assessment undertaken in two UK hospital trusts and one university setting.

Participants Patients who had recently undergone general abdominal surgery and healthcare professionals involved in post-surgical wound care.

Results Phase I: In the example case study, 19 relevant content domains were identified from two clinical tools, two patient questionnaires and 19 multistakeholder interviews (nine patients, 10 HCPs). Phase II: Domains were operationalised into items and subitems (secondary components to collect further information, if relevant). The version after pretesting had 16 items, five of which included further subitems. Plain language in conjunction with medical terminology was applicable in nine (27%) items/subitems. Phase III: Pretesting with 28 patients and 14 HCPs found that the UROM was acceptable to both respondent groups. An unanticipated secondary finding of the study was that the combined use of plain language and medical terminology during questionnaire development may be a useful, novel technique for evaluating item interpretation and thereby identifying items with inadequate content validity.

Conclusion UROMs are a novel approach to outcome assessment that are acceptable to both patients and HCPs. Combining plain language and medical terminology during item development is a recommended technique to improve accuracy of item interpretation and content validity during questionnaire design. More work is needed to further validate this novel approach and explore the application of UROMs to other settings.

Strengths and limitations of this study

- A novel approach to outcome assessment is described, comprising the use of plain language alongside medical terminology in questionnaire items to develop a single measure for completion by patients and/or healthcare professionals.
- Multiple stakeholders were considered in all phases of development of the new universal-reporter outcome measure (UROM).
- Combined use of plain language and medical terminology in items presents a novel technique for evaluating item interpretation and improving content validity during questionnaire development.
- Evaluation of this novel method is limited to the findings from a single case study. Further work is warranted to explore the applicability of UROMs to other settings.

BACKGROUND

Research often requires views from different stakeholders on the same subject. Reasons may be to combine different stakeholder responses to obtain comprehensive information to better answer the research question. Other reasons may be to compare stakeholder responses and explore any similarities or differences in perspectives, opinions or behaviours. Alternatively, there may be logistical reasons for obtaining views from different stakeholders to enable important data to be collected irrespective of who is available to provide it. In a clinical trial, for

example, the frequency and severity of symptoms and adverse events might be self-reported by the patient and/or judged by an observer, such as a healthcare professional (HCP).[1 2] In these situations, assessment tools and questionnaires are usually developed separately for use by specific stakeholder groups. Consequently, two different tools/questionnaires that intend to measure the same construct (concept) may use different terminology to suit the target audience. In the assessment of wounds for surgical site infection, for example, there are tools for clinical staff that use medical terminology such as 'purulent drainage' and 'spontaneous dehiscence'. Alternatively, separate patient-completed questionnaires use plain language descriptions asking patients, for example, about 'discharge or leakage of fluid' and whether the 'edges of the wound separated or gaped open'.

While separate stakeholder-specific tools may intend to measure the same constructs, uncertainty remains about whether this is achieved in practice. Evidence suggests that even minor alterations to item (question) wording can lead respondents to draw on different sources of information, subsequently affecting their responses.[3 4] It is likely, therefore, that the use of different stakeholder-specific terminology in separate tools for patients and for HCPs that intend to measure the same construct may introduce a degree of variation in the way that they are interpreted and subsequently the response that is provided. Specifically, differential understanding of items between individual respondents or stakeholder groups can compromise the measure's content validity or degree to which the content adequately reflects the construct being measured. This can have implications for drawing accurate conclusions when combining or comparing data collected from different stakeholder groups. Equitable interpretation of items by different respondents is therefore essential to ensure that the data collected by the separate measures are accurate and valid. It is hypothesised that developing a universal-reporter outcome measure (UROM) which uses a single set of terminology to collect data from either patients and/or HCPs may reduce variation in interpretation and thereby optimise the content validity of the measure. This study introduces the concept and method for developing a UROM, illustrated within a case study of surgical wound assessment.

METHODS

Case study: development of an outcome measure for surgical site infection (SSI)

The concept of a UROM originated as a solution to a problem within a feasibility study of surgical wound assessment. The feasibility study was performed to explore whether it would be possible to conduct a large randomised controlled trial (RCT) of different wound dressing strategies. The proposed primary outcome of the main RCT was surgical site infection (SSI) at 30 days post-surgery.[5] Assessment of SSI at this timepoint would typically be after the patient had been discharged from hospital and was recovering at home. At the time of the feasibility study, separate stakeholder-specific tools for evaluating surgical wounds to assess SSI were available for HCPs and for patients though they had several limitations.[6–10] The clinical tools for HCPs to complete, for example, were designed for use while patients were still in hospital, predominately used medical terminology and were complex to complete.[6 8] The questionnaires for patients were developed from a clinical perspective, did not involve patients in their development and had not been formally validated.[7 9] One aim of the feasibility study, therefore, was to develop and validate an outcome measure to assess wounds for infection that was suitable for use both in-hospital after the patient had been discharged. While it would have been possible to develop two separate stakeholder-specific measures, it was recognised that this may compromise the validity with which the construct of SSI was measured. A single UROM to evaluate surgical wounds, suitable for completion by patients or HCPs, was therefore developed.

Development of the UROM

The UROM was developed using established methods for developing new outcome measures[11 12], adapted to address specific issues relevant to developing a 'universal' measure for patient and/or HCP completion (table 1). The following sections provide a brief description of these unique considerations and adapted methods, drawing on the surgical wound case study as an example. A full description of the development and evaluation of the surgical wound outcome measure (including assessments of reliability, a comparison of patient and HCP responses and clinical validity) has been published elsewhere[13 14] and is outside the scope of this paper.

Table 1 Phases of UROM development

	Established methods for outcome measure development	Adapted/novel methods relevant to UROM development
Phase I	Identification of content domains	Emphasis on using a multistakeholder perspective to identify domains of importance.
Phase II	Item construction	A multistakeholder approach considering plain language in conjunction with medical terminology.
Phase III	Pretesting and evaluation of content validity	Cognitive interviews with multiple stakeholders.

UROM, universal-reporter outcome measure.

Phase I: identification of content domains using a multistakeholder perspective

The first phase in the development of any new measurement instrument typically involves the identification of important content domains (ie, areas of interest potentially relevant to include in the new tool). Typical sources include the existing literature and interviews with key stakeholders to elicit expert opinion and experience.[12] The focus of the UROM development was to consider patient and HCP perspectives together to identify domains of importance to either or both stakeholders for consideration to include in a single, universal tool.

In the case study, health domains (defined as the sign, symptom or wound care intervention relevant to SSI assessment and management) important to patients and HCPs for possible inclusion in the new SSI measure were identified using existing guidelines for questionnaire development.[11 15] First, a content analysis of the two most commonly used existing clinical tools identified in a previous systematic review,[16] and their two associated patient questionnaires, was undertaken. In addition, in-depth interviews with 19 stakeholders were conducted; nine patients who had experience of wound infection and 10 HCPs involved in post-surgical care. Details of the existing tools, the methods for analysing their content and the interview sampling strategy and data collection have previously been reported.[13] Importantly for the UROM, data from the analysis of existing tools and interviews were combined to provide a list of all the domains considered to be relevant to SSI assessment, irrespective of whether the source was from a patient's and/or a HCP's perspective.

Phase II: item construction using a multistakeholder approach; considering plain language in conjunction with medical terminology

The second phase in the development of a new measurement instrument usually involves the conversion or 'operationalisation' of domains (identified in phase I) into items for a questionnaire. For the UROM, a novel approach was applied to item construction; using both plain language and medical terminology wherever possible. The reason for doing this initially was to use language that was understood by, and was familiar to, each stakeholder group, to facilitate easy and timely completion of the outcome measure.

In the case study, the list of important SSI domains identified in phase I were considered for inclusion in the UROM. Domains considered to be unsuitable for patient report were excluded. Item construction was performed by four members of the case study team (JMB, RM, TM, BR), experts in the design and use of questionnaires including patient-reported outcome measures and professionals in the clinical field. First, plain language was used to describe the SSI domain in a clear and unambiguous way. Language was targeted for a lay audience without technical or medical terms, following standard recommendations.[12 15 17] Next, medical terminology (if it existed) relating to the SSI domain was included in parentheses at the end of the item. An example is illustrated in box 1.

Box 1 Example item showing plain language with medical terminology in parentheses

Was there redness spreading away from the wound? (erythema/cellulitis)

Response categories took the form of either a binary yes/no response or an ordinal scale (initially a five-point scale 'not at all', 'a little', 'moderately', 'quite a bit' and 'very much') as appropriate to the individual item. The remaining structure and layout of the questionnaire was designed to be simple, clear and straightforward for patients and/or HCPs to complete, in accordance with established guidelines. The UROM was produced in two formats. One format was a paper-copy questionnaire to post to patients after leaving hospital. The other format was a paper-copy case report form for HCPs to complete when conducting observer wound assessments either on the telephone or face to face as part of the wider feasibility study. Items and response categories were identical. The only minor difference was the use of first-person or third-person narrative, necessary for whether the tool was to be completed by a patient or an observer (box 2).

Phase III: pretesting and evaluation of content validity: cognitive interviews with multiple stakeholders

The third phase in the development of any new measurement instrument involves pretesting with a sample of participants from the target population. Asking potential recipients to complete early drafts of a new measurement instrument is critical for testing understanding, interpretation and identifying potential problems with its completion and use. Cognitive interviews are a valuable technique used during pretesting to examine content validity and ensure that items are comprehended as intended.[12 18] Pretesting of the case study outcome measure has previously been described in detail.[13] Methods of specific relevance to development of the UROM are emphasised and expanded below.

Participants and recruitment

In the case study, both patients and HCPs were invited to take part in cognitive interviews to pretest early versions of the measure. Patients were those who had recently undergone general abdominal surgery, identified and approached by research nurses/members of the study team in two UK hospital trusts. HCPs were those involved

Box 2 Example item showing first-person and third-person narrative

Has your wound been drained? (drainage of pus/abscess)
Has the wound been drained? (drainage of pus/abscess)

in post-surgical care, identified from the same hospital trusts and from the authors' university institution. Written information describing the study in detail was provided to all participants. Contact details of interested participants were passed on to members of the study team and followed up by telephone or email to further discuss the study, answer questions and arrange an interview. Interviews were conducted by two researchers (RM and TM) between January and August 2015. Written consent was obtained prior to each interview.

Cognitive interviews

Individual face-to-face cognitive interviews were conducted with participants to explore the overall acceptability, suitability and comprehensibility of the early versions of the UROM. The primary aim of the interviews was to examine the suitability of the UROM as an outcome measure for SSI. Specific objectives were to refine aspects of the questionnaire, including the layout, item phrasing, instructions and response categories. Additionally, and of specific relevance to development of a UROM, interviews explored views on items that included both plain language and medical terminology.

Participants were shown the questionnaire and asked to complete the items relating to their current experience (patients) or a recent or hypothetical patient case (HCPs). Participants were asked to vocalise their thoughts as they read and responded to each item using a 'think aloud' technique.[18] Completion of the questionnaire was observed by the researcher who then used probing questions to explore the participants' thoughts in more depth. Interpretation, accuracy and general opinions on the use of medical terminology alongside plain language in the questionnaire were sought. Question probes, for example, asking HCPs "Is (the plain language) a suitable description of the medical term?" were used to explore the accuracy of the item for measuring the intended underlying construct. Areas for investigation and specific items for discussion were identified and evolved throughout the course of interviews. Revisions were made to the provisional draft and new versions tested in subsequent interviews with new participants until findings indicated that no further revisions were required.

Data analyses

Interviews were audio-recorded and written up in descriptive memoranda summarising key findings and suggestions for improvements to the questionnaire. Selected relevant quotations were transcribed verbatim. Interviews, analyses and modifications to the questionnaire were performed as an iterative process so that revisions to the questionnaire could be explored in subsequent interviews. Two researchers (RM and TM) independently conducted and summarised interviews, cross-checking approximately 25% of audio-recordings and memoranda to maximise rigour and reliability of the findings.[19]

Table 2 Identified domains of importance for inclusion in the case study UROM for surgical wound assessment

Domain relevant to SSI assessment	Existing tool	
	Patient questionnaire(s)	Clinical tool(s)
1. Wound healing	✓	x
2. Wound heat	✓	✓
3. Wound redness	✓	✓
4. Wound discharge	✓	✓
5. Layers separating—spontaneous	✓	✓
6. Wound swelling	✓	✓
7. Wound pain	✓	✓
8. Fever	x	✓
9. Contact with healthcare professional	✓	x
10. Dressing needed	✓	x
11. Antibiotics needed	✓	✓
12. Layers separating—deliberate	x	✓
13. Hospital admission	✓	x
14. Drainage needed	x	✓
15. Wound cleaning	✓	✓
16. Abscess	✓	✓
17. Microbiology	✓	✓
18. Prolonged hospital stay	x	✓
19. Smell*	x	x

*Identified from stakeholder interviews.
SSI, surgical site infection; UROM, universal-reporter outcome measure.

Patient and public involvement

Patients and members of the public were involved throughout the study. Two patient and public representatives were included on the study steering committee. A meeting was held with a group of patients to discuss the design and conduct of the study and to refine patient-facing study documents.

RESULTS

Phase I: identification of content domains using a multistakeholder perspective

In the case study, 19 relevant content domains (covering SSI signs, symptoms and wound care interventions) were identified from the existing tools and in-depth interviews (table 2). Of these 19 domains, 18 were identified from at least one of the existing clinical tools and/or patient questionnaires and were supported by interview data. One domain (smell) was not identified in any existing tools but was found to be important in interviews with both patients and HCPs.

Phase II: item construction using a multistakeholder approach; considering plain language in conjunction with medical terminology

Seventeen of the 19 domains identified in phase I were developed into items for the first draft of the UROM. Two domains were excluded (microbiology and prolonged hospital stay) as they were considered unsuitable for patient report, and information could more reliably be obtained through other sources (eg, hospital records). All items were intended to be completed by all respondents, with some items having secondary components (subitems) to collect further information, where relevant. For example, if a participant responded to an item indicating that a symptom was present, further questions captured more details about that symptom.

The first draft of the UROM prior to pretesting included 13 items, of which six included secondary subitems to collect further information. Eight medical terms were included in parentheses after the plain language either in the items or secondary subitems. It was not applicable to include medical terminology in the remaining items because a medical description did not exist for the construct being addressed; for example, "Has the wound been smelly?". In the first draft, eight items had ordinal response categories and five items had binary yes/no response options. Responses of 'don't know' were also included to explore whether participants required this option and identify potentially problematic items to answer.

Phase III: pretesting and evaluation of content validity: cognitive interviews with multiple stakeholders

Forty-two cognitive interviews (with 28 patients and 14 HCPs) were conducted. Participant characteristics and interview duration are summarised in table 3.

Detailed findings from the pretesting phase of the case study SSI outcome measure have previously been reported.[13] Findings of particular relevance to UROM design are described in detail below.

Modifications to the UROM during pretesting

Throughout pretesting and the iterative process of interviews and revisions, the UROM was modified eight times. The final version after pretesting included 16 items for assessing SSI, with five having secondary subitems to collect further information. Nine medical terms were included in parentheses at the end of items/subitems (see online supplementary file 1).

General modifications (not specific to UROM design) included revision of the ordinal response categories from a five-point to a four-point scale ('not at all', 'a little', 'quite a bit' and 'a lot') because a middle category of 'moderately' was found to be uninformative. The filter question at the beginning of the measure ("Have you had any problems with the healing of your wound(s)?") was also dropped because data indicated that participants' answers to this filter question were often not concordant with their subsequent responses to subsequent items (eg, participants responded that they had no problems with wound healing but went on to report experiencing symptoms of problems with wound healing). General changes also included restructuring some items, for example, changing some secondary subitems to standalone items to minimise errors and reduce missing data.

Several changes were made to the provisional measure of specific relevance to UROM design. Most changes related to the use of plain language in conjunction with medical terminology. For example, one medical term (calor) was dropped as interviews revealed it was not a term that was used in current practice. Another medical term (spontaneous dehiscence) was added to an item where previously no medical description had been considered. Detail explaining the reason for this is provided below. In another item, one term (dressing) that was initially included in the plain language description was later moved to the end of the item in parentheses because interviews revealed that it was less understood by a lay audience than initially expected.

Table 3 Participant demographics and interview duration

	Number of participants (total n=42)
Patients, n (%)	28 (66.7)
HCPs, n (%)	14 (33.3)
Age, years (%)	
21–30	1 (2.4)
31–40	9 (21.4)
41–50	5 (11.9)
51–60	9 (21.4)
>60	18 (42.9)
Male, n (%)	21 (50.0)
Clinical expertise*	
General practitioner	3 (21.4)
Hospital/Research nurse/ midwife	4 (28.6)
Practice/Community nurse/ midwife	3 (21.4)
Surgical trainee	4 (28.6)
Surgery type,† n (%)	
Caesarean section	3 (10.7)
Upper GI	9 (32.1)
Lower GI	10 (35.7)
Hernia repair	6 (21.4)
Duration of interview, min	
Median (range)	25 (13–52)

*HCP participants only.
†Patient participants only.
GI, gastrointestinal; HCP, healthcare professional.

Box 3 Acceptability of items combining plain language and medical terminology

Participant: "I just skipped over it… I did say 'What's that?' but it didn't concern me because I could answer the question… I did make the comment of what [is that] but I didn't worry about it and I just went on to the next bit." Patient participant, 1107
Participant: "I was… you know… interested [in the medical terms]. I didn't look at all of it… um, a couple I thought was interesting because it was Latin. That's what I thought. And also spontaneous dehiscence… I thought, gosh… so yeah I found it quite interesting."
Interviewer: "Did you find them [medical terms] confusing?"
Participant: "No… For instance that first one… I don't think I even saw…" Patient participant, 1104
Participant: "If I was… on my own receiving this I am a bit of a google searcher so I would probably have looked them up." Patient participant, 2030

Box 4 Improved understanding and interpretation of items

Item: Was there redness spreading away from the edges of the wound? (erythema and cellulitis)

Participant: "In that first one [item], because I was describing the redness under the skin – more deeper redness, purple - when I read that first question, it was the fact that I had some idea of what erythema and cellulitis are… I thought, well it wasn't those…but ended up saying a little because of the redness… it probably was erythema… but I wasn't sure."
Interviewer: "And if we didn't have that erythema and cellulitis in there?…"
Participant: "Yeh, I would then have probably thought… that it was [asking about] that [bruising]… but because I recognised those [erythema and cellulitis]… I think I know more or less what those two things are." Patient participant, 1081

Acceptability of UROMs and items combining plain language and medical terminology

In general, neither patients nor HCPs reported significant concerns with the inclusion of medical terminology alongside plain language within the same item. Some patients reported that they found the medical terms interesting and educational. Other patients reported that they found the plain language alone sufficient for comprehension and therefore ignored or did not notice the medical terms (box 3). Concerns that medical terms may cause patients anxiety was raised in interviews with HCPs, although this was not supported by data from interviews with patients. One patient referred to the use of the Internet to look up medical terms but did not express any concerns about doing so (box 3).

Improved understanding and interpretation of items

An unanticipated secondary unexpected finding of the study was that the combined use of plain language and medical terminology may be a useful, novel technique for evaluating item understanding and improving item interpretation during the process of developing the measure. Findings from the pretesting interviews indicated that the inclusion of a medical term alongside plain language in an item directly affected the way that participants interpreted and subsequently responded to items, by facilitating their understanding of the item. One participant, for example, explained how the presence of the medical term improved their understanding of the item, thereby enabling them to respond more accurately. This participant reported that they would have interpreted the item differently, and therefore responded differently, had the medical term not been included (box 4).

Identification of items with inadequate content validity

Directly related to the finding that the use of plain language and medical terminology may improve participants' understanding and interpretation of items, the combined use of plain language and medical terminology during item development was found to be a useful technique to maximise the content validity of the outcome measure. The tandem use of medical terminology and plain language identified several items that were ambiguous or insufficiently reflected the construct that was intended to be measured. For example, it became apparent during interviews that some participants who read the plain language were interpreting an item differently to others who were also reading and understanding the medical terminology (box 5). In this example, quotes from patient participants demonstrated that the item was not being interpreted as intended, while quotes from the HCP participants indicated that the plain language description was not an adequate reflection of the medical terminology. This led to the item being modified to include more detail in the plain language description.

In addition to the finding that using both plain language and medical terminology from the outset of item development may improve the content validity of the outcome measure, there was some evidence to suggest that adding medical terminology to an item that had initially been written using only plain language may also maximise content validity. For example, interviews indicated that the plain language item "Have the edges of any part of the wound separated?" was not specific enough for measuring the intended construct (cases where the wound had spontaneously broken down or 'dehisced'). Specifically, the item was being interpreted too broadly by both patients and HCPs and was therefore interpreted to overlap with another later intended to measure the deliberate separation of the wound edges by a doctor or nurse ("Has your wound been reopened by a doctor or nurse?"') (box 6). A medical term ('spontaneous dehiscence') was added to this item and the plain language revised to "Have the edges of any part of the wound separated on their own accord". Subsequent interviews with HCPs indicated that, had this medical term not been included, the plain language alone may not have been interpreted to include more serious cases of wound breakdown.

Box 5 Improved content validity of the construct to be measured

Item: Has your wound been cleaned out? (debridement of wound)

Participant: "[reading] 'Has your wound been cleaned out?'… Yes it has been cleaned out…with this little plastic thing of liquid… saline stuff… They squirt this liquid in… put it on some gauze." Patient participant, 1083

Participant: "I think… urm… when I had the staples taken out I think it was pretty standard practice for the nurse to just clean the wound before.… I don't know what she put on but it was a bit of cotton wool and she just rubbed… something." Patient participant, 1104

Participant: "To me… cleaned out and debridement… isn't the same thing. Cleaned out is washing with saline and debridement is picking… slough… like yellow stuff out… or cutting dead skin away or scabs." Healthcare professional participant, 3000

Participant: "When you say cleaning out of the wound do you just mean, like, getting some water?…That [debridement] actually, to me, involves cutting… debridement is when you actually remove by cutting… or scraping… some dead tissue. Cleaned out, to me, just implies… oh, um, that you just gave it a bit of a clean… I completely understand what debridement of the wound means but, to me, cleaned out is not the same." Healthcare professional participant, 1142

Modified item: Has your wound been cleaned out to remove any dead tissue? (debridement of wound) draft version 6.0 10/04/2015

DISCUSSION

This article describes the novel concept of, and a method for developing, a UROM. This is a single questionnaire developed to measure a construct using data collected from either patients and/or HCPs by using a single set of terminology comprising both plain language and medical terminology. A UROM may be required for logistical reasons (as in the example case study) or it may be for other purposes when there is a need to combine or compare responses from different stakeholders. Development of a UROM includes established methods for developing new outcome measures,[11 12] uniquely adapted to address specific considerations and requirements of a UROM. These considerations include incorporating the views of all key stakeholders in all phases of UROM development and a novel approach to item construction by combining plain language alongside medical terminology.

Box 6 Improved content validity of the construct to be measured

Item: Have the edges of any part of the wound separated?

Participant: "So what does that one mean?… so… it is separated… because it's not stitched up"… The actual wound was left open because they couldn't stitch it up." Patient participant, 1079

Participant: "What does that [separated] mean—like cut or something? Got bigger?" Patient participant, 1076

Modified item: Have the edges of any part of the wound separated on their own accord? (spontaneous dehiscence) draft version 2.0 05/02/2015

Illustrated within a case study of surgical wound assessment, the findings from this study indicate UROMs are acceptable for completion by both patients and HCPs and ready for further evaluation in future work. An unanticipated secondary finding of the study was that the combined use of plain language and medical terminology during questionnaire development may be a useful, novel technique for evaluating item interpretation and thereby identify items with inadequate content validity. Development and use of a UROM is recommended for studies where it is appropriate and beneficial to measure a construct using data collected from either patients and/or HCPs.

The concept of a UROM, with items that combine plain language and medical terminology, represents a different approach to outcome measurement where traditionally tools for patients and HCPs are developed separately and used separately. Guidelines for the development of measurement instruments usually advise against the use of clinical or technical jargon (eg, medical terminology), particularly when the general public are the intended recipients.[12 20] In general, guidance recommends not to use medical terminology in patient literature to avoid any difficulty in understanding.[20–22] This study shows, however, that the use of medical terminology alongside plain language during the development of a measurement instrument can be beneficial for making sure items are interpreted as intended and reflect the intended construct to be measured. No patients in this study reported concerns with this approach.

To our knowledge, this is the first study to introduce and examine the concept of a UROM. The use of this method for ensuring content validity may be applicable and beneficial in a wider context. Within our research institution, for example, we have undertaken studies developing core outcome sets (COSs) for trials in oesophageal, colorectal and bariatric surgery where the views of patients and HCPs on the same subject were required.[23–25] A UROM, with items written in plain language and medical terminology in parentheses where appropriate, was used to collect the opinions of both patients and HCPs and prioritise outcomes of importance.[23–25] This concept is now recommended to COS developers as one approach to consider for describing outcomes to stakeholder groups.[26] Other potential advantages of using UROMs rather than separate questionnaires for patients and HCPs include: (1) the need for a single study to develop the tool rather than separate studies for patient and HCPs measures; (2) a more streamlined and efficient way of collecting outcome data, with easier administration and reduced costs by using the same measure and (3) ease of data synthesis as data from multistakeholders can be readily combined. Further work to examine the applicability of UROMs to different settings would be beneficial.

This study has several strengths. It is the first study, to our knowledge, to describe a UROM; an outcome measure intentionally developed for patient and healthcare professional completion. One-to-one cognitive interviews with patients and HCPs also allowed for a detailed examination of item comprehension and acceptability of a single tool combining plain language and medical terminology in both stakeholder groups. UROMs are a novel concept and, currently, their evaluation is limited to the findings from this single case study. The potential advantages of the UROM design for improving content validity identified in this study was an unanticipated finding, however, and was not a primary focus of the case study interviews. The number of direct examples for its evaluation are, consequently, limited. The exact extent and nature to which medical terminology influences participants' responses warrants further investigation. In box 4, for instance, it is assumed that the respondent was clearer or more accurate with their response as a direct result of reading the medical term. The possibility that the medical term may have introduced uncertainty, 'noise' or measurement error was not formally explored. The detailed validation of the SSI outcome measure and the accuracy of the tool for assessing wound infection has been reported in full elsewhere[14], however, did not explore this possibility.

In summary, a novel approach to outcome assessment and development of a UROM is described. Findings have shown that combining plain language and medical terminology within items can improve content validity. It is a recommended technique for the development of outcome measures in other situations where information from both patients and HCPs is required. Further work is now needed to explore the applicability of UROMs in other settings within and outside the field of surgical research.

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Contributors RM designed and pretested the measure, analysed and interpreted the cognitive interview data within the context of the wider case study and drafted the manuscript. SB was a major contributor in writing the manuscript. JB was the chief investigator for the BIuebelle study and was the major contributor for the concept of designing universal-reporter outcome measures. KA was a major contributor in writing the manuscript. All authors read and approved the final manuscript.

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Appendix 4. PHE SSISS post-discharge questionnaire (PDQ)

Hospital number	
Full name	
Date of birth	

To be completed by hospital staff
Or place addressograph

Staff use only.
Please enter your hospital name, address and the name of the person responsible for collecting the questionnaire at the hospital in this box.

Surgical wound healing post discharge questionnaire

Serial Number __/__/__/__/__/__/__/__/__/__ **Date of birth** ___/___/_____

Category of procedure _____

Date of operation ____/____/____ **Date form to be completed** ____/____/____
(30 days after operation)

Dear Patient,

We are monitoring all patients with surgical wounds, to detect patients who develop wound infection after surgery.

Please complete the following questionnaire and return it in the envelope provided on the 30th day after your operation *(See above for this date)* ***or as soon as possible after that day.***

Please fill in the date you completed this questionnaire ____/____/____

Have you had any problems with the healing of your wound?

❒ **YES** ❒ **NO**

If you have answered **NO** you do not need to continue with the rest of the form but it is very important that you return it to the hospital in the envelope provided. Thank you for taking the time to do this. **If you have answered YES, please read the following carefully and complete the rest of the form.**

Since you were discharged from hospital after your operation have you noticed any of the following symptoms?

Was there any discharge or leakage of fluid from any part of the wound?

❒ Yes ❒ No
If yes, was it either;

❒ Clear or blood stained
❒ Yellow/green (pus)
❒ Other-please specify _____

Form designed by *Surgical Site Infection Surveillance Service*, Public Health England. July 2009

Please tick any of the following additional symptoms that applied to your wound:

- ❒ Pain or soreness in addition to the discomfort experienced following the operation.
- ❒ Redness or inflammation spreading from the edges of the wound.
- ❒ The area around the wound felt warmer/hotter than the surrounding skin.
- ❒ The area around the wound became swollen
- ❒ The edges of any part of the wound separated or gaped open.

Did any health care worker take a sample from your wound to send to the laboratory?
❒ Yes ❒ No

If you saw a health care worker because of these symptoms, please indicate who you saw from the list below-

- ❒ GP
- ❒ District nurse
- ❒ Midwife
- ❒ Doctor or nurse at the hospital
- ❒ Other – please specify
- ❒ Did not see one about my wound

Please tell us the date you noticed these symptoms.
If you cannot remember the exact date, please give an approximate date _____/____/_____

Have you been prescribed antibiotics for an infection in the wound?
❒ Yes ❒ No

If yes, who prescribed them? _____

Have you been re-admitted to hospital with an infection of the surgical wound?
To the hospital at which the operation was carried out? ❒ Yes ❒ No
To another hospital? ❒ Yes ❒ No

If yes, which one? _____

Other comments_____

For Office Use Only: (To be completed by surveillance co-ordinator only)

Patient reported SSI meets definition ❒ Yes ❒ No

If yes enter criteria for SSI-

❒ Criterion 1 Discharge pus + antibiotics prescribed
❒ Criterion 2 Clinical signs* + dehiscence
❒ Criterion 3 Clinical signs* + antibiotics prescribed

*Clinical signs- at least 2 of pain, heat, redness or swelling.

Enter criteria selected into weblink record for this patient.

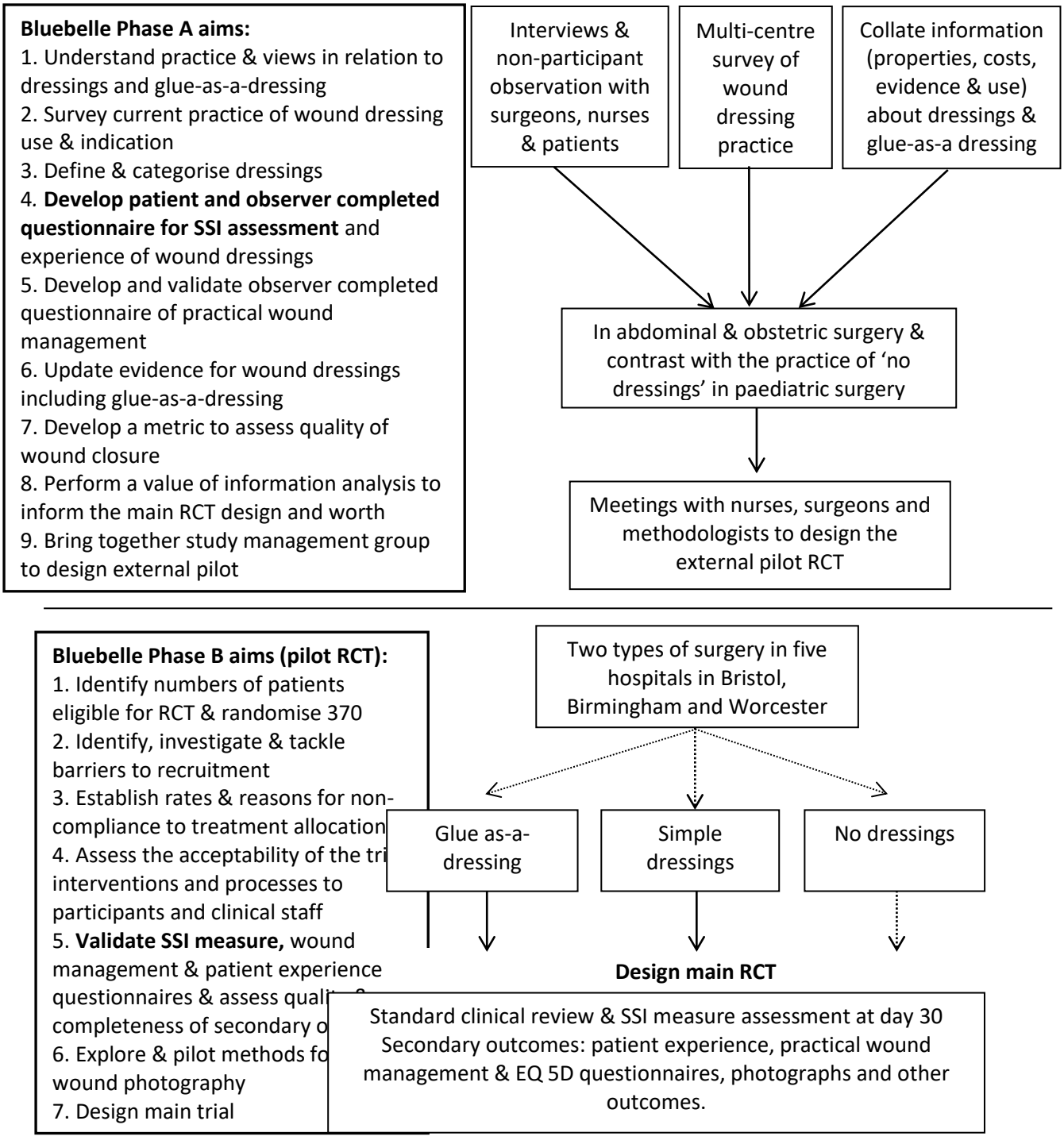
Note: Do not report stitch abscess (discharge confined to points of suture penetration, minimal inflammation)

Form designed by *Surgical Site Infection Surveillance Service*, Public Health England. July 2009

Appendix 5. Items from the ASEPSIS-associated patient questionnaire

Questionnaire item	Response
Have the wounds healed without any problems at all?	Yes ❑ No ❑
If 'yes' please ignore the following questions. If 'no' please answer the following:	
1. Has the wound been red?	Yes ❑ No ❑
2. Has the wound discharged clear yellow fluid?	Yes ❑ No ❑
3. Has the wound discharged pus?	Yes ❑ No ❑
4. Has the wound broken open?	Yes ❑ No ❑
5. Have you been given antibiotics for wound infection?	Yes ❑ No ❑
6. Has a district nurse had to dress the wound?	Yes ❑ No ❑
7. Has a doctor opened/drained an abscess?	Yes ❑ No ❑
8. Have you been admitted to hospital elsewhere?	Yes ❑ No ❑
9. Has the wound been opened and cleaned under general anaesthetic in hospital?	Yes ❑ No ❑

Appendix 6. A schematic overview of the Bluebelle feasibility study
The development and validation of the SSI measure were embedded within the wider study (highlighted in bold font)



Bluebelle study

Patient Information Leaflet

Study interviews

The Bluebelle Study: a feasibility study of complex, simple and absent wound dressings in elective and unplanned surgery

Local Principal Investigator:
<Insert PI name and contact details>
Email:
Tel:
Local contact details:
<Insert coordinator name and contact details>

Trust study number (local site): <insert details>
HTA reference: 12/200/04
REC No: 14/LO/0640

Contact details

Bluebelle Research Team
<Insert local research team address>
Tel: <Insert local telephone>
Fax: <Insert local fax>

Email: bluebelle-study@bristol.ac.uk

Contents

PATIENT INFORMATION LEAFLET

BLUEBELLE
A feasibility study of complex, simple and absent wound dressings in elective and unplanned surgery

You are being invited to take part in a research study. Before you decide whether to take part or not, you need to understand why the research is being done, and what it would involve for you. Taking part in research is voluntary; it is up to you to decide to join the study. You are free to withdraw at any time, and if you choose not to take part or to withdraw from the research, you do not have to give any reason for your decision. Nobody will be upset, and the standard of care you receive will not be affected if you decide not to take part.

Please take time to read the following information carefully. **One of our team will go through the information leaflet with you, explain the study in more detail, and answer any questions you have**. If anything is not clear or you would like more information, do not hesitate to ask a member of the local research team (see contact details on page 2). Talk to others about the study if you wish, such as friends or relatives, and take time to decide. If you would like to take part, you will be asked to

confirm by signing a separate consent form and will be given a copy for your records.

What is the purpose of the study?
There are many different types of wound dressings that can be used following common operations. These can be relatively simple and inexpensive, or can be complex and therefore more expensive. At the same time, for some operations, and particularly those where the patients are children, it is quite common for no dressing to be used.

Bluebelle is a study looking at the use of wound dressings following common operations including caesarean section. It is really interested in finding out if a dressing is needed at all and whether this changes the chances of developing a wound infection after surgery.This is a very important question to answer, as minimising this risk will have clear benefits for patients, doctors, nurses and the health service generally. At present we do not know whether dressings reduce the risk of infection.

We are currently in the first phase of the Bluebelle study. This phase is trying to understand patients', doctors' and nurses' views about the use of surgical wound dressings after common operations. This is important so that the research team can judge whether it is possible to conduct a full scale clinical research study comparing the dressings and no dressings and decide which types of operation might be included in such a study.

We are also developing questionnaires for future patients

to complete after their surgery, to ask about the wound and how it has been healing. In order to do this, we want to interview patients who have had surgery to find out more about their experience and examine whether the questionnaires we are developing are suitable, acceptable and easy to complete.

Why have I been invited to take part in an interview?
You have been invited to take part because you are scheduled to have, or have already had, elective or unplanned general surgery or caesarean section, or because you have previously had surgery and developed a wound infection.

What will happen to me if I take part?
You will be asked to take part in a one-off research interview with a member of the Bluebelle research team.

Where will I meet the researcher?
You will meet the researcher at a time and place that is most convenient to you. For example, it may be most convenient if the researcher was to visit you at home or another venue of your choosing. Interviews will be conducted in quiet, confidential settings. The researcher will contact you to discuss and agree upon a time and place that is most convenient for you.

How long will an interview last?
We expect that interviews will last between 30 and 45 minutes. However, it might be sensible to allow a little more time, perhaps an hour, so that the researcher will

have chance to answer any questions you might have about the research.

What exactly will happen?
The researcher will meet with you, check that you understand all of the information about the study and that you are still willing to take part. They will ask you to sign a consent form to confirm this. An interview is simply an informal discussion with the researcher. They will speak to you in order to understand your perspective on the use of wound dressings for the operation you are scheduled to have / have just had. We are interested to hear your views and experience of this, to understand what is important to you about this topic. We are also interested to hear your views on how likely patients (like you) are to consider taking part in a full scale clinical study of wound dressings, for example if there was a chance of receiving no wound dressing, and what you think might influence other patients' decisions to take part.

We would welcome your ideas about things that you feel the research team might need to consider during a study of wound dressings, and particularly things that are likely to be important from a patient's perspective. If you are being interviewed about the new questionnaires we are developing, you will be asked to go through the questions and give feedback (e.g. your understanding of the question, how easy it is to answer, how relevant it is to your experience). We are interested to hear how you think the questionnaire can be improved.

Will there be any long-term follow up?
Unless you so wish, after the interview we will not contact you again, other than to update you on the findings of the research if you wish to receive a summary at the end of the research.

Will information I give be confidential?
Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. Procedures for handling and storing your information will be compliant with the Data Protection Act 1998.

All information which is collected about you and that you give us during the course of the research will be kept strictly confidential. The information that will be collected includes personal information such as your name, address and NHS number, to allow us to keep in touch with you during your participation in the research. The information collected will be stored in a secure database held at the co-ordinating centre, and will only be accessed by authorised members of staff involved in the research. This includes the hospital research team and staff at the coordinating centre who are managing the research.

Your medical notes will need to be seen by authorised members of the hospital research team, and representatives of the sponsor's office at UHBristol so they can collect information needed for this research study. The confidentiality of your medical records will be respected at all times.

Under no circumstances will you be identified in any way in any report arising from the study.

Do I have to take part?
It is up to you to decide. We will describe the study and go through this information leaflet, which we will then give to you. If you decide to take part, we will ask you to sign a consent form to show you have agreed to take part.

What are the possible disadvantages and risks of taking part?
Taking part in this study will involve being interviewed. If you feel the interview is causing undue distress or emotional discomfort, you can end the interview at any time. You may request a break at any time during the interview process. If at any time you change your mind, you may withdraw from the study without giving a reason and without your medical or legal rights being affected.

What are the possible benefits of taking part?
Some people find that taking part in interviews helps them talk through their views and experiences, and that this can be helpful for them. The information we will get from the study will be very helpful to the NHS and to future patients needing operations that carry a risk of wound infection that might be influenced by the use of wound dressings.

The discussions will be recorded – will they be confidential?
The interview conversation will be recorded, with your consent, so that the researchers can listen to them again and make a written record (transcript) of the discussion. Your name will not be used and we will remove information that we think might mean that other people can recognise you. Only the research team members will have access to the written accounts of the recordings.

The transcripts will be kept in a safe and secure place, so that they cannot be seen or heard accidentally or easily stolen. Similarly, digital files of the recordings will be held on secure encrypted equipment and computer networks at the University of Bristol. You have the right to check the accuracy of data held about you and correct any errors.

What if there is a problem?
If you have any concerns or questions about this study, please contact the research team listed on page 2. Alternatively you can discuss these with the member of the research team who will conduct the interview. Please feel free to ask any further questions before deciding to take part in the study, or at any time during the study.

The study team know of no risks of physical or significant psychological harm that could be caused by you participating in the interviews and therefore if you are affected or harmed by taking part, there would be no special compensation arrangements. However, if harm

occurs as a result of someone's negligence, then you may have grounds for a legal action, but you may have to pay for this yourself. Irrespective of this, the normal National Health Service complaints mechanisms would still be available to you should you wish to complain, or have any concerns about any aspect of the way you have been approached or treated, during the course of this study.

If you have concerns about any aspect of the way you have been approached or treated during the course of this study you may wish to contact the hospital's Patient Support and Complaints Team:

<Local details>
Email:
Tel:
Minicom number:

What will happen if I don't want to carry on with the study?
You can withdraw from the study at any time and without giving a reason. A decision to withdraw at any time or a decision to not take part will not affect the standard of care you receive. If you withdraw, any information collected before your withdrawal will be kept and used for the research.

What will happen to the results of the study?
Researchers will review all of the results from the discussions to identify important themes and issues. We

will report these to the wider research team so that they will influence the second part of the Bluebelle study, the pilot (test) clinical study of wound dressings. We will also report results to the funders of the research and hope to publish them in appropriate academic and professional journals and at conferences. We will provide you with a summary of the final results if you wish.

Who is organising and funding the research?
The research is funded by National Institute for Health Research Health Technology Assessment Programme Project No. 12/200/04). The University Hospitals Bristol NHS Foundation Trust has overall responsibility for conduct of the study, which is a collaboration with the University of Birmingham. The research is being organised and run on their behalf by the Clinical Trials and Evaluation Unit, University of Bristol.

Who has looked at the study?
All research in the NHS is looked at by an independent group of people called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by London - Camden & Islington ethics committee.

Any questions and what next?
If you are interested in talking to a researcher about your experiences or have any questions regarding this study please do not hesitate to contact the local research team (details on page 2).

Further information
You can obtain **general information on clinical research** from the UK Clinical Research Collaboration (UKCRC) who produce a booklet called "Understanding Clinical Trials". This provides in-depth information on the design and conduct of clinical trials and aims to answer the questions of those considering taking part.

Electronic copies can be downloaded from the UKCRC website:
www.ukcrc.org/publications/informationbooklets.aspx.

Printed copies can be requested by emailing:
info@ukcrn.org.uk

Or contacting:
UK Clinical Research Collaboration,
20 Park Crescent,
London, W1B 1AL
Tel: 020 7670 5452.

General information about research can also be found at <insert local details> or there are leaflets available if you would like to be sent one. Please ask.

Thank you for taking the time to read this leaflet.

NHS
National Institute for Health Research

Appendix 8. Topic guide for interviews with patients to identify content domains for the SSI measure (Study 1; Phase 1)

Opening

Interviewer will re-iterate study information and purpose of interview, answer any questions, and take written consent.

Background, interviewee detail and ice breaker

Interviewee background and details of procedure that the interviewee has had, how long in hospital, when discharged.

Patients experience of wound infection

Discuss the patient's experience of wound infection following planned surgery, including signs and symptoms and health care use. Note to the patient that they may or may not have experienced some of the signs/symptoms and health care use that are mentioned; we are talking to people with different experiences and asking a range of questions to capture these experiences.

Signs/symptoms

Experience of wound healing

- Can you tell me about the healing of your wound after your operation? (Probe: where is your wound, have you looked at your wound, are you able to see your wound: what does/did it look like (discharge, redness, swelling, opening) what does it feel like (pain, heat), have you noticed any smell from you wound?)
- Have you noticed/did you notice any problems with the healing? (Probe: what are/were the problems, when did you notice problems, has an infection been identified, how is your wound now, has it healed and if yes when did it heal e.g. 5/10 days after surgery?)
- Have the problems with your wound healing affected your life in general? (Probe: How -sleep, functioning, relationships, work, for how long, and how has this made you feel? Did the wound healing affect others in your life?)

Discharge [if not covered in above]

- Have you noticed/did you notice any discharge from your wound? (Probe: where/what does/did it look like, when did this occur – before/after/during

identified problems and/or wound infection, how long did it last/do you still have discharge?)

Redness [if not covered in above]

- Have you noticed/ did you notice any redness of your wound? (Probe: where/what does/did it look like, when did this occur – before/after/during identified problems and/or wound infection, how long did it last/is it still red?)

Swelling [if not covered in above]

- Have you noticed/did you notice any swelling of your wound? (Probe: where, when did it occur – before/after/during identified problems and/or wound infection, how long did it last/is it still swollen?)

Pain [if not covered in above]

- Have you experienced any pain or soreness with your wound? (Probe: where/how painful, when did this occur – before/after/during identified problems and/or wound infection, were painkillers taken – what and how often, how long did this last/is it still painful?)

Heat [if not covered in above]

- How does/how did your wound feel to touch? (Probe: cool/warm, where, when did any heat occur – before/after/during identified problems and/or wound infection?)

Opening [if not covered in above]

- Have you noticed/did you notice your wound breaking open? (Probe: where, when did this happen – before/after/during identified problems and/or wound infection?)

Smell [if not covered in above]

- Have you noticed/did you notice any smell from your wound? (Probe: when did it occur – before/after/during identified problems and/or wound infection, how long did it last/does it still smell?)

Other signs/symptoms

- You've talked about various things you noticed about your wound (reiterate what) are there any other things you, or other people, have noticed/noticed about your wound healing?

Severity of wound infection/problems

- How long did the infection/ problems with your wound last? (Probe: in hospital/post discharge)
- Were there any things that helped with the healing of your wound? (Probe: what, when and how?)
- Were there any things that did not help the healing of your wound? (Probe: what, when and how?)

Health care use: interventions and investigations

[Cover below topics if not already covered in relation to signs/symptoms above]

- Have you talked to/seen any health professionals about your wound problems/infection? (Probe: who, when, why, about what, what happened (e.g. dressings, drainage, x-ray, biopsy, another operation), how often?) [Focus discussion as relevant: in hospital stay/post discharge and who made contact: patient or health professional]
- Have you had your dressing changed? (Probe: how often, by whom, can/did you see your wound when the dressing was changed?)
- Increased observation [if not covered in above]
- Did a health professional look at your wound while in hospital? (probe: how often, what did they look at/do/ask?)
- Did a health professional look at your wound after returning home? (probe: how often, when, where, what did they look at/do/ask?)
- Investigations [if not covered in above]
- Has a health professional ever taken a sample from you wound? (Probe: when, how did your wound look/feel at the time, what happened?)
- Interventions [if not covered in above]
- How long were you in hospital after your operation? (Probe: where, when discharged)
- Have you been given/were you given any medications for your wound infection/problems? (Probe: what (e.g. antibiotics), when (in hospital/post discharge), by who, how did your wound look/feel at the time, how long taken for?)

- Did you need to go back to hospital for problems with your wound/wound infection? (Probe: why, where, when, what happened (e.g. dressings, drainage, x-ray, biopsy, another operation))?

Current measures

I have two questionnaires here that are currently used to assess problems with a patient's wound after they have been discharged from hospital.

We would value your feedback on how easy or difficult these questionnaires are to complete and if you think they ask useful questions. Would you mind completing these questionnaires? If you have any thoughts as you are completing the questionnaire, or don't understand what the question is asking or how to answer a question please let me know. I will also ask you some questions after you have completed the questionnaire. [Make a note of any issues talked about during the process to probe on these in more depth once the questionnaire is complete]

<u>ASEPSIS-based PDQ</u>

- How did you find completing this questionnaire? (Probe: easy/difficult – which questions and why? Did the questions make sense? Were they relevant to your experience – not at all, a little, quite a bit, very much? Do the response categories [explain this] make sense? Are you able to answer the questions using a yes/no answer – relate back to patients experience?)

Question specific

- I noticed/you mentioned that question X may have been/was confusing? (Probe: what does this question mean to you? Was it easy to answer – why/why not?)
- What does question [4/5/6] mean to you? What do you understand by the term [discharge/clear yellow fluid/pus/broken open]?
- Was it easy to answer question [2/7/8/9/10]? (Probe why/why not? How could these questions be improved? Response categories?)
- Do you have any other suggestions on how the questionnaire could be improved? (Probe: alternative wording, additional questions, response categories, layout/presentation, length of questionnaire?)

<u>CDC-based PDQ (PHE SSISS)</u>

- How did you find completing this questionnaire? (Probe: easy/difficult – which questions and why? Did the questions make sense? Were they relevant to your experience – not at all, a little, quite a bit, very much? Do the response

categories [explain this] make sense? Are you able to answer the questions using the response categories provided – relate back to patients experience? Why/why not?)

Question specific

- I noticed/you mentioned that question X may have been/was confusing? (Probe: what does this question mean to you? Was it easy to answer – why/why not?)
- What does question [2] mean to you? What do you understand by the term [discharge/leakage/ clear or blood stained/yellow green pus]?
- Was it easy to answer question [1/2/3/4/5/6/7/8]? (Probe why/why not? How could these questions be improved? Response categories?)
- Do you have any other suggestions on how the questionnaire could be improved? (Probe: alternative wording, additional questions, response categories, layout/presentation, length of questionnaire?)

General

- When after your discharge from hospital do you think would be the best time to complete a questionnaire? (Probe: Why? Methods of receiving and returning questionnaire -person, post, (SAE for return) email?)

Closing

Interviewer checks understanding of any outstanding points, answers further questions, and checks to see if interviewee would like to receive a summary of findings.

Appendix 9. Topic guide for interviews with healthcare professionals to identify content domains for the SSI measure (Study 1; Phase 1)

Opening

Interviewer will re-iterate study information and purpose of interview, answer any questions, and take written consent.

Background, interviewee detail and ice breaker

Details of interviewee role and working history in role.

Experience of SSI – lead in

1) **I understand in your role as _____ you come into contact with patients experiencing wound infections after surgery.**

OR

2) **I understand in your role as _____ you have experience of detecting wound infections in patients that develop after surgery.**

Surgeons, ward nurses, tissue viability nurses and other staff who come into contact with patients and may be involved in identifying and treating wound infections.

Signs/symptoms

Q. As you know wound infections are common. Can you tell me what would prompt you to treat a wound as infected? *(Probe: why, what signs/symptoms or other information tell you it is infected? Does presence of pus require any treatment? How long after surgery do you see infections - in hospital/post discharge? Who is involved in the treatment of infections and why? How is the infection treated?)*

Health care use: interventions and investigations.

Q. If a patient has a wound infection what follow-up is required? *(Probe: observation - when, where, how often, and by whom; swabs; biopsy; xray; surgery; drainage; other? Why, how long after surgery, how often, does this vary by severity of infection, differences between in hospital/post discharge, who is involved at what stage, would anything else happen?)*

Q. Do you routinely swab wounds? *(Focus on participant on them taking/asking for the swab. Probe: why, when?)*

Microbiologists, methodologists and others who may be involved in detecting SSI but not necessarily involved in treating infections.

Q. Can you tell me about your experience of identifying wound infections in patients who have had surgery? *(Probe: what information is used to identify infection, how long* after surgery is this information obtained, how is this information obtained, who is involved in identifying infection, how is the information used, who is contacted, do you have any contact with patients and if so why?)

Current measures of SSI

In the Bluebelle trial we would like to find an effective way of measuring wound infection. Measures currently used widely include the Centre for Disease Control and Prevention (CDC) criteria and the ASEPSIS grading scale.

Q. Are you familiar with either of these measures? *(Probe: which measure, have you used them? If yes when, why, how often?)*

We are interested in finding out how easy or difficult these current measures are to use and would value your feedback.

I have some pictures of a wound infection, with brief patient background, and a copy of the current clinician measures.

Provide patient background scenario **and** picture (mild to moderate wound infection) and ask participant to run through patient reported questions.

Using these criteria/this grading scale how would you classify this wound? ***If you have any comments or questions about the measures while you are doing this please do let me know.***

Following questions to be asked after classification of wound pictures:

CDC criteria

Q. How did you find using these criteria to classify wound infection? *(Probe: Easy/difficult, why, which criteria?)*

Q. Do you think the criteria used are relevant? *(Probe: Why/why not? Are any more relevant than others – why/why not and when?)*

Q. Do you think the distinctions between superficial, deep, and organ/space infections are useful? *(Probe: why/why not? If yes who are they useful for – the hospital/patient and how are they useful?)*

Q. Do you have any suggestions on how these criteria could be improved? *(Probe: How, why, are there any other criteria which could be included?)*

ASEPSIS

Q. How did you find using the grading scale? *(Probe: Easy/difficult, why, which parts?)*

Q. Do you think the criteria used to identify wound infection are relevant? *(Probe: Why/why not?)*

Q. Do you think it is useful to grade wound characteristics over five days? *(Probe: Why/why not?)*

Q. Do you think it is useful to assess the proportion of the wound affected? *(Probe: Why/why not?)*

Q. Do you have any suggestions on how this grading scale could be improved? *(Probe: How, why, what other items could be included?)*

General

Q. Do you have any other suggestions about things to consider when measuring wound infection? *(Probe: why, when?)*

Q. Discharge of patients after surgery is happening earlier than previously. We are thinking about the times at which we should measure presence of infection. If measuring it within 30 days, when during this timeframe do you think it is useful to try and measure this? *(Probe: how often? Does this vary depending on the type of surgery? Appropriate person to complete?)*

Q. Patient reported measures have been developed to identify wound infection 30 days after surgery. Do you think it is possible for patients to identify if they have

a wound infection? *(Probe: why/why not, if yes what questions do you think is it relevant to ask patients, and why? Is 30 days after surgery a good timeframe?)*

I have the patient measures here. Do you have any comments on these?

Closing

Interviewer checks understanding of any outstanding points, answers further questions, and checks to see if interviewee would like to receive a summary of findings.

Appendix 10. Topic guide for cognitive interviews to pre-test the SSI measure (Study 1; Phase 3)

Opening

- Ensure participant understands about the study and purpose of this interview (the Bluebelle study is looking at the use of wound dressings after surgery. As part of this study we are designing a questionnaire for patients to complete after they have been discharged from hospital, to monitor the healing of the wound and look for signs of wound infection. We would like to get feedback on the questionnaire so far)
- Answer any questions
- Ask if participant is happy for the interview to be audio-recorded, explain the recording will be kept confidential, will be anonymised (names, addresses etc will be removed) and all data will be stored securely
- Obtain written consent (version 1.0) – check all sections have been initialled, signed and dated

Explain to the participant that the interview will be in 3 parts:

1) Answering some general questions about their surgery and experience
2) Completing a questionnaire and "thinking out loud" – verbalising their thoughts while answering the questions. Remind them that we are interested in their feedback – how easy/difficult they find the questions and whether it covers what happened to them
3) Discussing their views after finishing the questionnaire - asking further comments on their understanding of the questions and any suggestions for improvements

Background of surgery and wound healing experience

- Ask brief details of the surgical procedure that the participant has had. Include type of surgery and whether it was lap or open.
- Determine how long it has been since their operation and how many days they initially spent in hospital
- Ask for brief information about any problems with wound healing – *(Probe: what were the first signs, when did you noticed any problems, what did you do, what advice did you seek, who did you see, what treatment was given?*

Completion of the SSI measure

Explain the questionnaire the participant will now be asked to complete is one that we are designing for a research study. It is a questionnaire for patients who have had surgery so that we can monitor wound healing and look for any signs of wound infection. Make it clear that this is a work-in-progress and we would value their

feedback so that we can make improvements. Explain the information they provide is not going to be fed back to the clinical team.

- Ask the participant to complete the questionnaire to the best of their ability and based on their own experience. There are no right or wrong answers.
- Ask them to complete the questions based on what has happened in the last *two weeks.*
- Ask the participant to 'think out loud' as they complete the questionnaire, verbalising their thoughts and tell you what they are thinking and how they are choosing your answers. **"Tell me what you are thinking and how are you coming up with your answers".** Remind them that we can go back to any questions and talk in more depth when they have finished the questionnaire
- Ask them to let you know if they don't understand the question or are struggling to answer it accurately (e.g. if they cannot tick any of the response options)

Document on a paper copy of the questionnaire any reported issues or problems during the process to probe on these in more depth once the questionnaire is complete

When the participant has completed the questionnaire

<u>For each or select items</u>

- **Can you tell me in your own words what that question was asking?** (Probe: *What does the word XX mean to you? Are there any other ways you would describe it?*
- **Was it easy to choose an answer?** *(Probe: What does "a bit" "moderate" "very much" mean to you with regards to XXX (e.g. pain, leaking fluid). Are you able to answer the question accurately? Relate back to the patients' own experience)*
- Explore where participants have indicated confusion
- Choose two items to explore where the patient has <u>not</u> indicated symptomatology or difficulty to check false negatives

<u>General</u>

- **How did you find completing this questionnaire?** (Probe: *Were the questions relevant to your experience – are there any others that should be included? Do the response categories [explain this] make sense?)*
- **What does the word "wound" mean to you?**
- **Do you have any other suggestions on how the questionnaire could be improved?** *(Probe: alternative wording, additional questions, response categories, layout/presentation, length of questionnaire?)*
- Timeframe - **You have given your answers based on the last *two weeks.* Would your answers differ if you were thinking about just the last week? Or since you were discharged from hospital?** *(Probe: Why? Relate back to the patients' own experience. When do you think would be the best time to complete questionnaires like these?)*
- Explore views on methods for receiving and returning questionnaire – *in person, by post, (SAE for return) email?*

Other signs, symptoms, wound healing interventions

- **Can you tell me anything else you noticed about your wound that has not been covered in these questions?** *(Probe: we you able to look at your wound after the operation? what does/did it look like (discharge, redness, swelling, opening) what did/does it feel like (pain, heat), have you noticed any smell from you wound?)*
- **How long did the problems with your wound healing last?** (*Probe: in hospital/post discharge*)

Closing

- Check understanding of any outstanding points
- Answer further questions
- **If not previously completed, interviewer completes form A2 (1), and A2 (2) as relevant.**
- Thank the participant for their time and explain how they have helped – what we will do next

Patient Information Leaflet

Wound healing questionnaire sub-study

The Bluebelle Study: a feasibility study of complex, simple and absent wound dressings in elective and unplanned surgery

<Trust Logo>

Local Principal Investigator:
<Insert PI name and contact details>
Email:
Tel:
Local contact details:
<Insert coordinator/clinician name and contact details>

Trust study number (local site):
HTA reference: 12/200/04
REC No: 14/LO/0640

Contact details

Bluebelle Research Team
<insert contact details>
Email: bluebelle-study@bristol.ac.uk

Contents

PATIENT INFORMATION LEAFLET

BLUEBELLE

A feasibility study of complex, simple and absent wound dressings in elective and unplanned surgery

You are being invited to take part in a research study. Before you decide whether to take part or not, you need to understand why the research is being done, and what it would involve for you. Taking part in research is voluntary; it is up to you to decide to join the study. You are free to withdraw at any time, and if you choose not to take part or to withdraw from the research, you do not have to give any reason for your decision. Nobody will be upset, and the standard of care you receive will not be affected if you decide not to take part.

Please take time to read the following information carefully. **One of our team will go through the information leaflet with you, explain the study in more detail, and answer any questions you have**. If anything is not clear or you would like more information, do not hesitate to ask a member of the local research team (see contact details on page 2). Talk to others about the study if you wish, such as friends or relatives, and take time to decide. If you would like to take part, you will be asked to confirm by signing a separate consent form and will be given a copy for your records.

What is the purpose of the study?

The main Bluebelle study

There are many different types of wound dressings that can be used following common operations. These can be relatively simple and inexpensive, or can be complex and therefore more expensive. At the same time, for some operations, and particularly those where the patients are children, it is quite common for no dressing to be used.

Bluebelle is a study looking at the use of wound dressings following common operations including caesarean section. It is really interested in finding out if a dressing is needed at all and whether this changes the chances of developing a wound infection after surgery. This is a very important question to answer, as minimising this risk will have clear benefits for patients, doctors, nurses and the health service generally. At present we do not know whether dressings reduce the risk of infection.

We are currently in the first phase of the Bluebelle study. This phase is trying to understand patients', doctors' and nurses' views about the use of surgical wound dressings after common operations. This is important so that the research team can judge whether it is possible to conduct a full scale clinical research study comparing the dressings and no dressings and decide which types of operation might be included in such a study.

The questionnaire sub-study

We are also developing a questionnaire for future patients to complete after they have been discharged from hospital, to monitor the healing of the wound and look for

any signs of infection. We would like to test the questionnaire with a group of people who have recently had surgery. We will ask these people to complete a questionnaire about how their wound has been healing and undergo telephone and/or face to face wound assessment with a doctor, nurse or midwife. This information leaflet is inviting you to take part in this questionnaire sub-study.

Why have I been invited to take part?

You have been invited to take part because you are scheduled to have, or have recently had, elective or unplanned general surgery or a C-section.

What will happen to me if I take part?

A member of the research team will come and speak to you after you have had your surgery. They will give you the opportunity to ask any questions and have further explanation as to what the study entails. They will ask you some questions about yourself and the surgery you have had, and ask you to complete a short questionnaire about your general health. The researcher may also ask to see you wound(s) and take a photograph.

Around 30 days after your surgery, we will ask you to complete and return a questionnaire that focuses specifically on your wound and how it has healed. This questionnaire will be sent to you by post with a stamped addressed envelope for its return. The questionnaire will take around 10-15 minutes to complete. You will also be asked to complete a short questionnaire about your

general health and a feedback ('debriefing') questionnaire which collects your opinion on the wound healing questionnaire and how easy or difficult it was to complete. You may be telephoned by the research team to collect further feedback or to remind you to post back the questionnaires if we do not receive them.

Around 30 days after your surgery, you will receive a short telephone call (approximately 10 minutes) from one of the study doctors, nurses or midwives to ask about your wound and how it has been healing. They may also invite you to have a face to face assessment so they can look at your wound(s). This appointment can be arranged at a venue of your choice (at home or in the hospital). At the appointment you may be asked if your wound can be photographed.

Some people will be sent a wound healing questionnaire at around 15 days after surgery (as well as 30 days after surgery) as we are interested in seeing if a second questionnaire provides added information about wound healing. A further group of people will be asked to complete the questionnaire twice within a few days apart (e.g. at 25 and 30 days after surgery) to help us investigate how consistent the questionnaire is.

What do I have to do?
After you have met the researcher and discussed the study, if you wish to take part the researcher will ask you to sign a consent form. You will be given a copy of the consent form and this information leaflet to keep. You will

be asked to provide your contact details so that the research team can send you the questionnaire and telephone you around 30 days after you surgery to ask how your wound has been healing.

Will I be paid expenses?
Travel expenses will be available for any additional visits you make to the hospital specifically for the purpose of this research, for example if you are invited for a face to face wound assessment around 30 days after your surgery. Travel expenses can not be paid if you attend the research visit at the same time as you are attending the hospital for another clinical appointment, for example for a routine follow-up appointment.

Will there be any long-term follow up?
Unless you so wish, after the 30 day assessment we will not contact you again, other than to update you on the findings of the research if you wish to receive a summary at the end of the research.

Will information I give be confidential?
Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. Procedures for handling and storing your information will be compliant with the Data Protection Act 1998.

All information which is collected about you and that you give us during the course of the research will be kept strictly confidential. The information that will be collected includes personal information such as your name, address and NHS number, to allow us to keep in touch

with you during your participation in the research. Any questionnaires that you complete or photographs of your wound will become part of the study data set. The information and data collected will be stored in a secure database held at the University of Bristol, and will only be accessed by authorised members of staff involved in the research. This includes the hospital and university research teams and staff at the co-ordinating centre who are managing the research.

Your medical notes will need to be seen by authorised members of the hospital research team, and representatives of the sponsor's office at UHBristol so they can collect information needed for this research study. The confidentiality of your medical records will be respected at all times.

Under no circumstances will you be identified in any way in any report arising from the study.

Do I have to take part?
It is up to you to decide. We will describe the study and go through this information leaflet, which we will then give to you. If you decide to take part, we will ask you to sign a consent form to show you have agreed to take part.

What are the possible disadvantages and risks of taking part?
Taking part in this study will involve completing questionnaires and being asked about how your wound has been healing. If you feel these assessments are causing undue distress or emotional discomfort, you can end them at any time. You may request a break at any

time during the wound assessment process. If at any time you change your mind, you may withdraw from the study without giving a reason and without your medical or legal rights being affected.

What are the possible benefits of taking part?
The information we will get from the study will be very helpful to the NHS and to future patients needing operations that carry a risk of wound infection that might be influenced by the use of wound dressings.

What if there is a problem?
If you have any concerns or questions about this study, please contact the research team listed on page 2. Please feel free to ask any further questions before deciding to take part in the study, or at any time during the study.

The study team know of no risks of physical or significant psychological harm that could be caused by you participating in the questionnaire sub-study and therefore if you are affected or harmed by taking part, there would be no special compensation arrangements. However, if harm occurs as a result of someone's negligence, then you may have grounds for a legal action, but you may have to pay for this yourself. Irrespective of this, the normal National Health Service complaints mechanisms would still be available to you should you wish to complain, or have any concerns about any aspect of the way you have been approached or treated, during the course of this study.

If you have concerns about any aspect of the way you have been approached or treated during the course of this study you may wish to contact the hospital's Patient Support and Complaints Team:

<Insert Local Details>
<Address Line 1>
<Address Line 2>
<Address Line 3>
<Address Line 4>
Email:
Tel:
Minicom number:

What will happen if I don't want to carry on with the study?
You can withdraw from the study at any time and without giving a reason. A decision to withdraw at any time or a decision to not take part will not affect the standard of care you receive. If, after completing the questionnaires or clinical assessment you decide to withdraw, we will ask you to tell us what you would like us to do with any information that have already been collected. Information collected up to the point at which you decide to withdraw is still valuable for the study. Therefore, we will ask whether you want the information destroyed, or whether we can use the information but without having any further contact with you. We will also ask whether we can continue to follow your progress using standard NHS records, without contacting you.

What will happen to the results of the study?
The results of the research will not be known until some time after the last patient has entered the study. The results may be reported in medical journals or presented at meetings but your identity will not be disclosed. During the course of the study we will ask you if you would like to receive a summary of the results by post after the research has finished.

Who is organising and funding the research?
The research is funded by National Institute for Health Research Health Technology Assessment Programme Project No. 12/200/04). The University Hospitals Bristol NHS Foundation Trust has overall responsibility for conduct of the study, which is a collaboration with the University of Birmingham. The research is being organised and run on their behalf by the Clinical Trials and Evaluation Unit and the School of Social and Community Medicine, University of Bristol.

Who has looked at the study?
All research in the NHS is looked at by an independent group of people called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by London - Camden & Islington ethics committee.

Any questions and what next?
If you are interested in talking to a researcher about your experiences or have any questions regarding this study please do not hesitate to contact the local research team (details on page 2).

Further information
You can obtain **general information on clinical research** from the UK Clinical Research Collaboration (UKCRC) who produce a booklet called "Understanding Clinical Trials". This provides in-depth information on the design and conduct of clinical trials and aims to answer the questions of those considering taking part.

Electronic copies can be downloaded from the UKCRC website:
www.ukcrc.org/publications/informationbooklets.aspx.

Printed copies can be requested by emailing:
info@ukcrn.org.uk

Or contacting:
UK Clinical Research Collaboration,
20 Park Crescent,
London, W1B 1AL
Tel: 020 7670 5452.

General information about research can also be found at www.uhbristol.nhs.uk/research or there are leaflets available if you would like to be sent one. Please ask.

Appendix 12. Consent form for participants for the cohort study to validate the SSI measure (Study 1, Phase 4)

Trust study number: SU/2013/4338
HTA reference: 12/200/04
REC No: 14/LO/0640
Mr Robert Longman
University Hospitals Bristol NHS Trust
Dept of Coloproctology
Level 7, King Edwards Building,
Bristol Royal Infirmary, Upper Maudlin Street,
Bristol, BS2 8HW Tel: 0117 342 3066

University Hospitals Bristol NHS
NHS Foundation Trust

Patient Study ID ☐

Patient Consent Form (wound healing questionnaire sub-study)

The Bluebelle Study: a feasibility study of complex, simple and absent wound dressings in elective and unplanned surgery

Please ask the patient to complete the following:		***Patient** to tick Yes/No and initial*		
		Yes	***No***	***Initials***
1.	Have you read and understood the Information Leaflet: wound healing questionnaire sub-study? (dated ____/____/____, version _____)	☐	☐	☐
2.	Have you had an opportunity to ask questions about the study and received satisfactory answers to your questions?	☐	☐	☐
3.	Have you received enough information about the study?	☐	☐	☐
4.	To whom have you spoken? _____			
5.	Do you understand that you are free to withdraw from the study at any time without giving a reason and that withdrawing from the study will not affect your medical care or legal rights?	☐	☐	☐
6.	Do you give permission for sections of your medical records to be looked at by individuals from the study research team, the regulatory authorities or the hospital trust overseeing the research? Do you give permission for these individuals to have access to your records and understand that strict confidentiality will be maintained?	☐	☐	☐
7.	Do you give permission for the study team to contact your GP with questions relating to the research study?	☐	☐	☐
8.	Do you agree to take part in this study, which involves completing a wound healing questionnaire and being contacted approximately 30 days after surgery for a wound assessment?	☐	☐	☐
9.	Do you agree to have photographs taken of your wound approximately 30 days after surgery (if you prefer not to have photographs taken, your participation in the rest of the study will not be affected)?	☐	☐	☐

Name of patient	Signature	Date
Name of person taking consent	Signature	Date

1 copy for patient; 1 for research team (original); 1 to be kept with hospital notes

Bluebelle Patient Consent Form: wound healing questionnaire sub-study
Version 2.0 3rd September 2015

Appendix 13. Version of the SSI measure for field-testing (Study 1; Phase 4)

Study ID: | | | | | | |

Bluebelle study

Wound healing questionnaire

Post-discharge questionnaire for patients

Your initials _____ Today's date __/__/____
d d m m y y y y

Completing the questionnaire

We are interested in knowing how your wound(s) have healed since your operation. Please complete this short questionnaire yourself. It is fine to ask someone else to write the answers for you or help answer some of the questions, for example if you have not been able to see your wound(s).

If you have more than one wound, please answer the questions **thinking about just one wound**—either your main wound or another wound if there have been any concerns about how it has been healing. We would like you to think about the wounds on your skin rather than any wounds that may be inside your body.

The information that you provide will remain confidential and anonymous. When you have completed the questionnaire, please return it in the pre-paid envelope provided.

Please turn over.....

UNIVERSITY OF BIRMINGHAM

University of BRISTOL

University Hospitals Bristol NHS Foundation Trust

North Bristol NHS Trust

University Hospitals Birmingham NHS Foundation Trust

Study ID: ☐☐☐☐☐☐

A. Your wound

The following questions ask about how your wound has healed since you left hospital after having surgery. It includes some problems that may occur with wound healing. Please note these are only possibilities and do not occur for many people. The words in brackets are the medical terminology. Please tick the box that is most relevant to your experience.

Since you left hospital after having surgery....	Not at all	A little	Quite a bit	A lot
1. Was there redness spreading away from the wound? (erythema/cellulitis)	☐	☐	☐	☐
2. Was the area around the wound warmer than the surrounding skin?	☐	☐	☐	☐
3. Was any part of the wound leaking fluid?	☐	☐	☐	☐

If "**Not at all**", go to question 4

a) Was it clear fluid? (serous exudate)	☐	☐	☐	☐
b) Was it blood-stained fluid? (haemoserous exudate)	☐	☐	☐	☐
c) Was it thick and yellow/green fluid? (pus / purulent exudate)	☐	☐	☐	☐
d) I do not know ☐				

	Not at all	A little	Quite a bit	A lot
4. Have the edges of any part of the wound separated/gaped open on their own accord? (spontaneous dehiscence)	☐	☐	☐	☐

If "**Not at all**", go to question 5

a) Did the skin separate?	☐	☐	☐	☐
b) Did the deeper tissue separate?	☐	☐	☐	☐
c) I do not know ☐				
5. Has the area around the wound become swollen?	☐	☐	☐	☐
6. Has the wound been smelly?	☐	☐	☐	☐
7. Has the wound been painful to touch?	☐	☐	☐	☐
8. Have you had, or felt like you have had, a raised temperature or fever? (fever >38°C)	☐	☐	☐	☐

Study ID: ☐☐☐☐☐☐

B. Wound care since your surgery

This section includes questions about wound care following your surgery. Please remember these are only possibilities and do not occur for many people. Please tick the box that is most relevant to your experience or write your answers where requested.

Since you left hospital after having surgery....

		Yes	No
9.	Have you sought advice because of a problem with your wound, other than at a planned follow-up appointment?	☐	☐
	If "**Yes**", please tell us who you sought advice from:		
	a) A doctor or nurse at the GP surgery/medical centre/walk-in centre	☐	☐
	b) A doctor or nurse at the hospital	☐	☐
	c) A midwife or health visitor	☐	☐
	d) Another health advisor	☐	☐

Please describe who the other health advisor was _____

		Yes	No
10.	Has anything been put on the skin to cover the wound? (dressing)	☐	☐
	If "**Yes**",		
	a) Was this done by a doctor or nurse at the GP surgery/medical centre/ walk-in centre?	☐	☐
	b) Was this done by a nurse/midwife/health visitor at home?	☐	☐
	c) Was this done by you/your partner/friend/family member?	☐	☐
	d) Was this done by a doctor/nurse/midwife at the hospital?	☐	☐
	e) Please describe what was put on to cover the wound		

_____

		Yes	No
11.	Have you been back into hospital for treatment of a problem with your wound?	☐	☐

Study ID: | | | | | | |

Since you left hospital after having surgery....

		Yes	No	Don't know
12.	Have you been given antibiotics for a problem with your wound?	☐	☐	☐
	If "**Yes**",			
	a) Were the antibiotics given as tablets/liquid?	☐	☐	☐
	b) Were the antibiotics given via a drip?	☐	☐	☐

If you know the name of the antibiotic(s) you have taken, please write it here

_____

If you answered "**Don't know**" please tell us why you are unsure

_____

		Yes	No	Don't know
13.	Have the edges of your wound been deliberately separated by a doctor or nurse?	☐	☐	☐
14.	Has your wound been scraped or cut to remove any unwanted tissue? (debridement of wound)	☐	☐	☐
15.	Has your wound been drained? (drainage of pus /abscess)	☐	☐	☐
16.	Have you had an operation under general anaesthetic for treatment of a problem with your wound?	☐	☐	☐

Do you have any other comments to tell us about the healing of your wound?

Thank you for completing this questionnaire.

This research is funded by the National Institute for Health Research Health Technology Assessment programme (Project No. 12/200/04)

Appendix 14. Debriefing questionnaire for the SSI measure (Study 1; Phase 4)

Patient ID……

Bluebelle study

Wound healing questionnaire sub-study
Debriefing questionnaire

Complete these questions after you have completed the wound healing questionnaire

a. How long did it take to complete the questionnaire?

less than 5 mins	☐	16-20 mins	☐
6-10 mins	☐	21-30 mins	☐
11-15 mins	☐	More than 30 mins	☐

b. Did you need help to answer any of the questions? Yes ☐ No ☐

If yes, please list the questions you had help with (e.g. number 3, number 10)

_____

Please let us know the reason you had help

_____

_____

_____

c. Were there any questions that you found confusing or difficult to answer? Yes ☐ No ☐

If yes, please state which questions and why

_____

_____

_____

Please let us know any other comments you have about the questionnaire

Thank you very much for completing these questions

This research is funded by the National Institute for Health Research Health Technology Assessment programme (Project No. 12/200/04)

Appendix 15. PHE SSISS data collection form

Appendix **4**

Public Health England

Surgical Site Infection Surveillance Service

Post Discharge Surveillance Data Sheet

Surgical category: _____ **Serial Number:** ___/___/___/___/___/___/___/___/___/___

First Name, Surname: **NHS No.** **Hospital Record No.:** **Date of Birth:** ___/___/____			**Surveillance year:** __ __ __ __ **Surveillance period** [Jan-Mar] or [Apr-Jun] [Jul-Sep] or [Oct-Dec] **Date of Admission:** ___/___/___ **Date of Operation:**___/___/____
30th day post-op: ___/___/___	**Date reviewed** ___/___/___		**Review location:**
SURGICAL SITE INFECTION	**Type of SSI**	**Date of onset SSI**	**For CABG indicate site of SSI**
❑ Yes ❑ No Please see definitions on back of form	❑ Superficial ❑ Deep ❑ Organ/space	___/___/__	❑ Chest incision ❑ Donor site incision

For organ/space SSI indicate specific site

❑ Arterial or venous	❑ Mediastinum (mediastinitis)
❑ Bone(osteomyelitis)	❑ Meningitis
❑ Breast abscess (mastitis)	❑ Myocardium or pericardium (myocarditis or pericarditis)
❑ Endocardium	❑ Other female reproductive tract (not vaginal cuff)
❑ Gastrointestinal	❑ Spinal abscess (without meningitis)
❑ Intra-abdominal	❑ Vaginal cuff
❑ Intracranial abscess	❑ Vertebral disc space
❑ Joint or bursa	

Symptoms/Comments:

Criteria for SSI *(indicate all that apply)*

- ❑ Abscess or other evidence of infection found during re-operation, by radiology or histopath examination
- ❑ Aspirated fluid/swab of surgical site yields organisms **and pus cells** are present
- ❑ Clinician's diagnosis
- ❑ Fever (temperature 38ºC or more)
- ❑ Heat
- ❑ Incision spontaneously dehisces or opened by surgeon
- ❑ Localised pain and tenderness
- ❑ Localised swelling
- ❑ Purulent drainage
- ❑ Redness

Your role	Staff name	Phone number	Ward/Hospital/Practice

Appendix 16. ASEPSIS grading scale

TABLE I—POINTS SCALE FOR THE DAILY WOUND INSPECTION

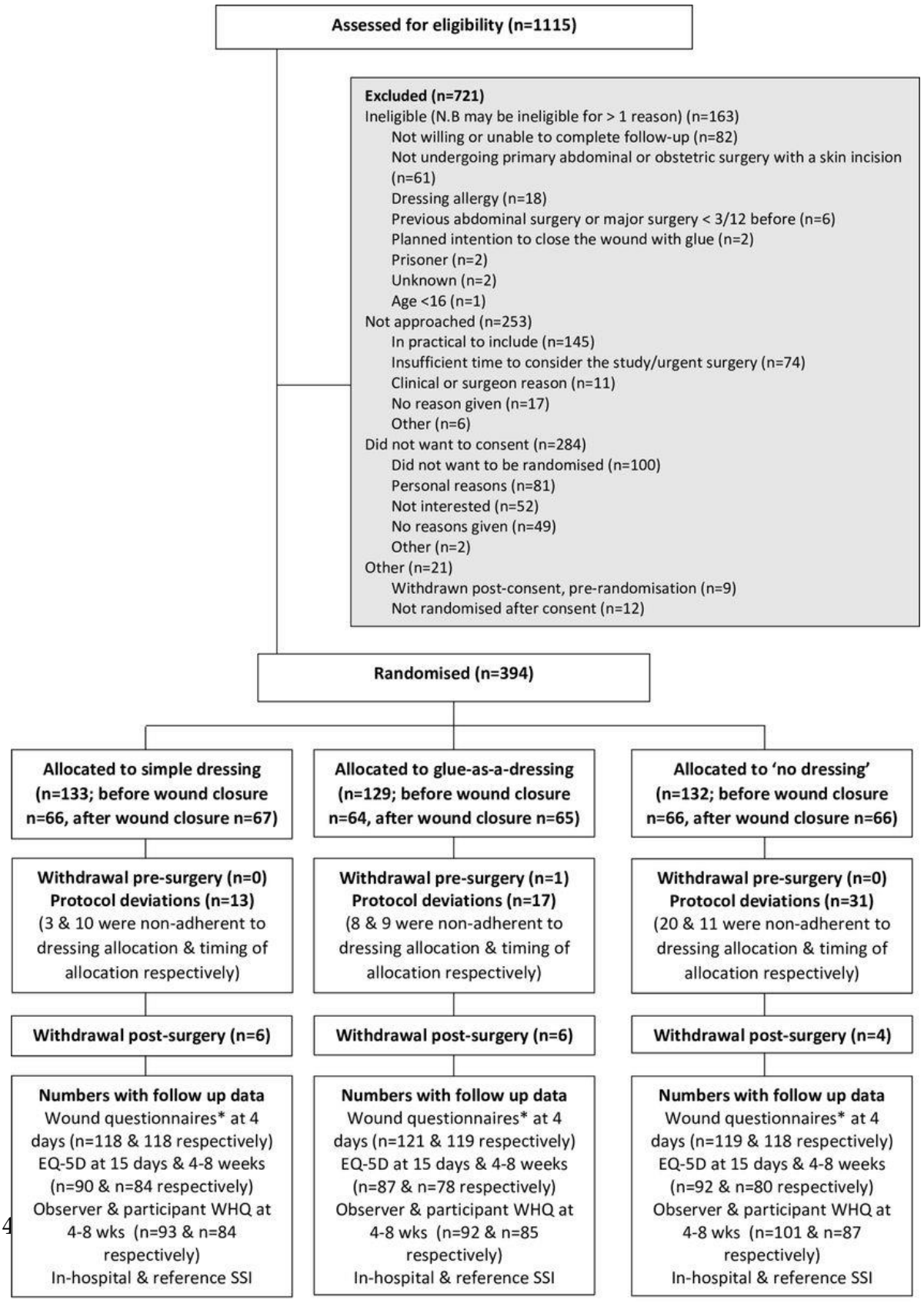
Wound characteristic	Proportion of wound affected (%)					
	0	<20	20–39	40–59	60–79	>80
Serous exudate	0	1	2	3	4	5
Erythema	0	1	2	3	4	5
Purulent exudate	0	2	4	6	8	10
Separation of deep tissues	0	2	4	6	8	10

TABLE II—THE WOUND SCORE: ASEPSIS

Criterion	Points
Additional treatment:	
Antibiotics	10
Drainage of pus under local anaesthesia	5
Debridement of wound (general anaesthesia)	10
*Serous discharge**	daily 0–5
*Erythema**	daily 0–5
*Purulent exudate**	daily 0–10
*Separation of deep tissues**	daily 0–10
Isolation of bacteria	10
Stay as inpatient prolonged over 14 days	5

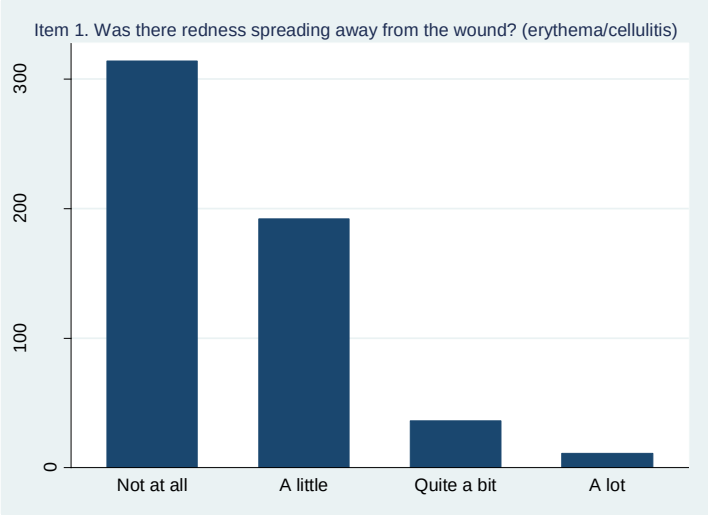
*Given score only on 5 of first 7 postoperative days.
Category of infection: total score 0–10 = satisfactory healing; 11–20 = disturbance of healing; 21–30 = minor wound infection; 31–40 = moderate wound infection; >40 = severe wound infection.

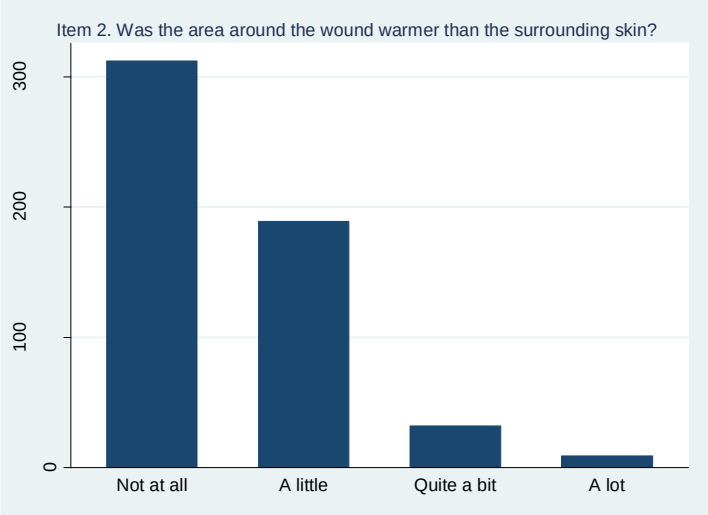
Appendix 17. Flow diagram of participants in the Bluebelle pilot RCT

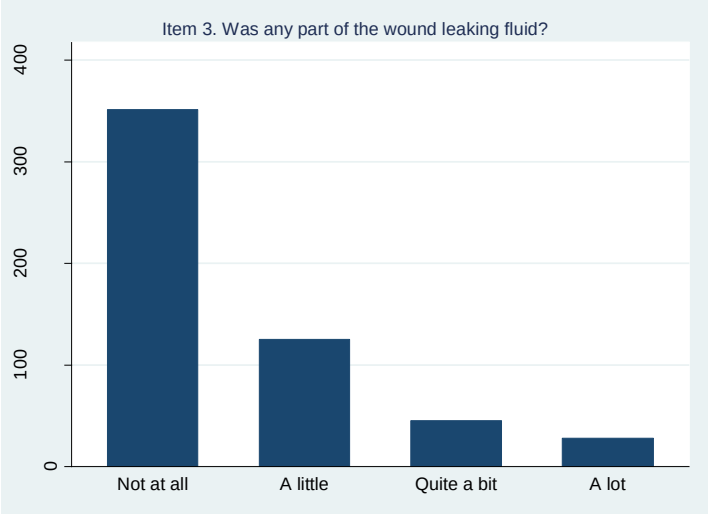


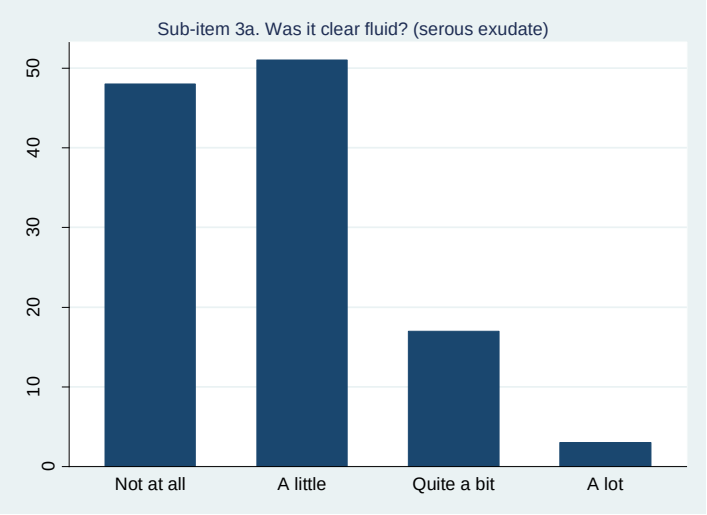
Withdrawal pre-surgery as surgery cancelled. Withdrawals post-surgery: participant preference (n=9), death (n=2), randomisation failed in theatre (n=2), clinician chose to withdraw participant (n=2), and one participant required emergency re-operation. WHQ: Wound Healing Questionnaire, SSI: Surgical Site Infection

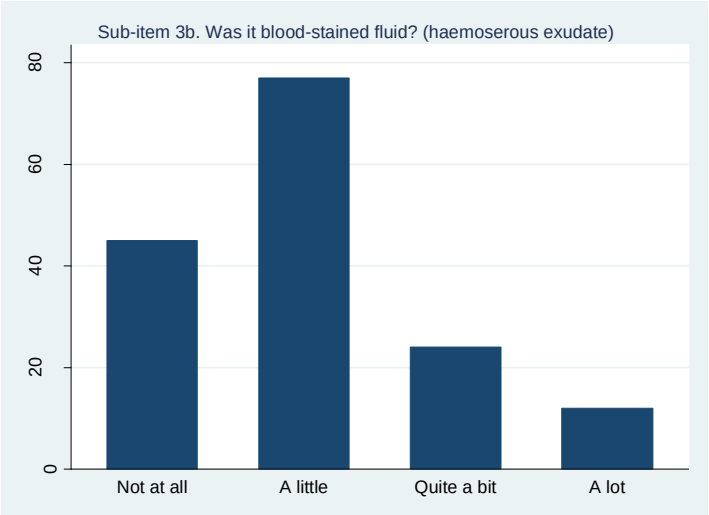
Appendix 18. Graphical representation of distribution of responses for items from participant self-assessments

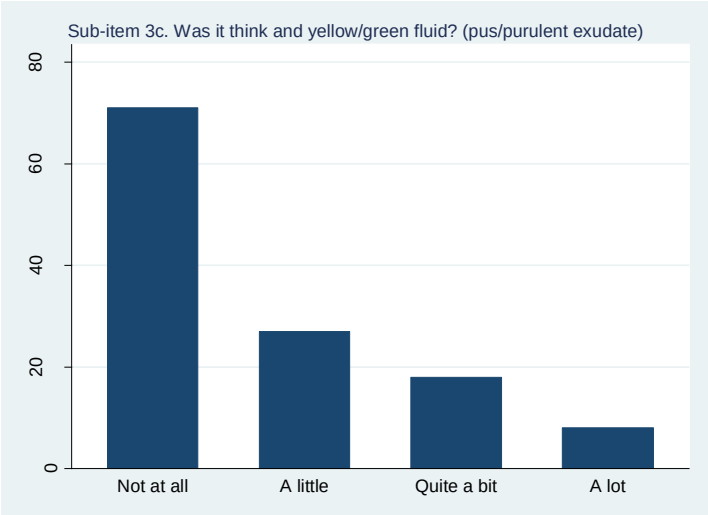


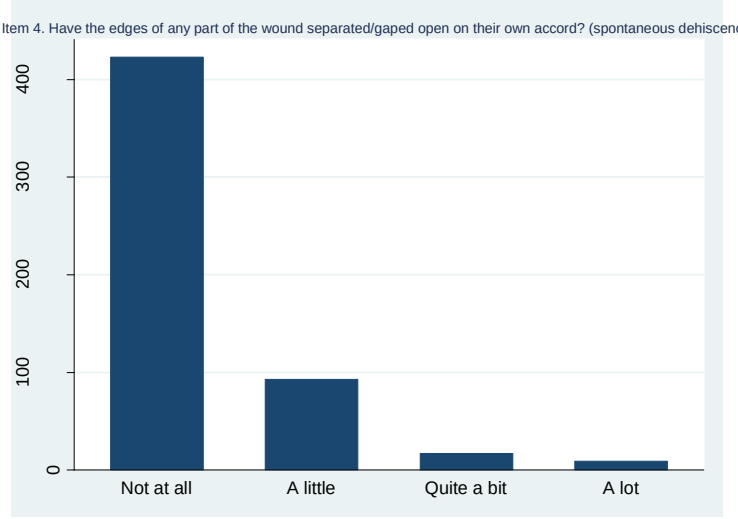


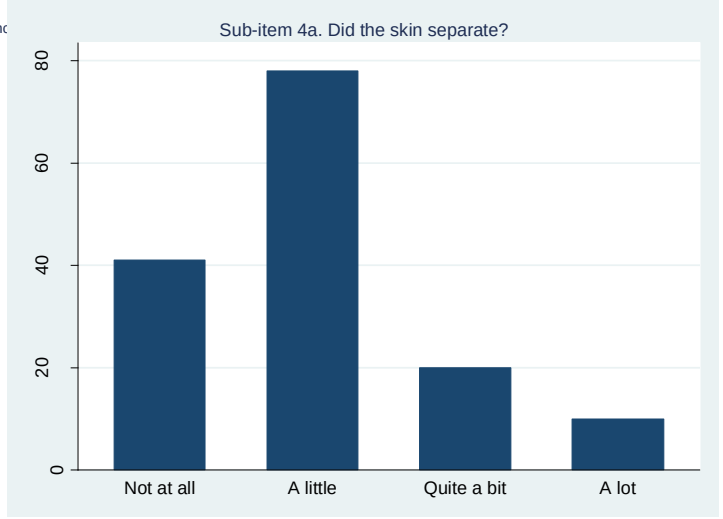


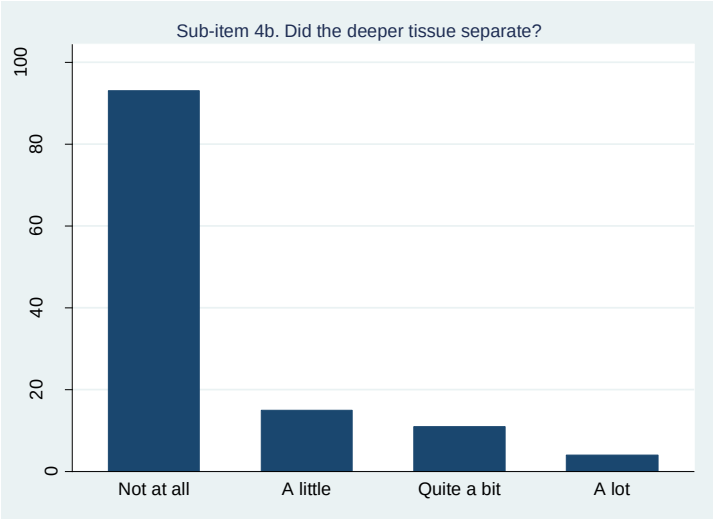


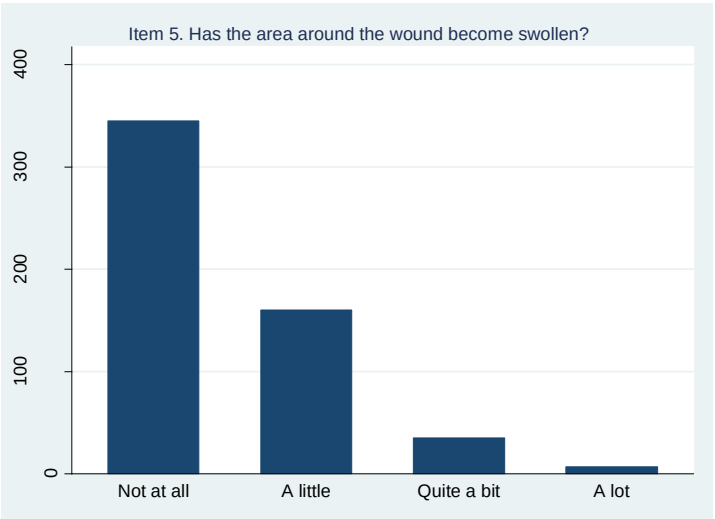


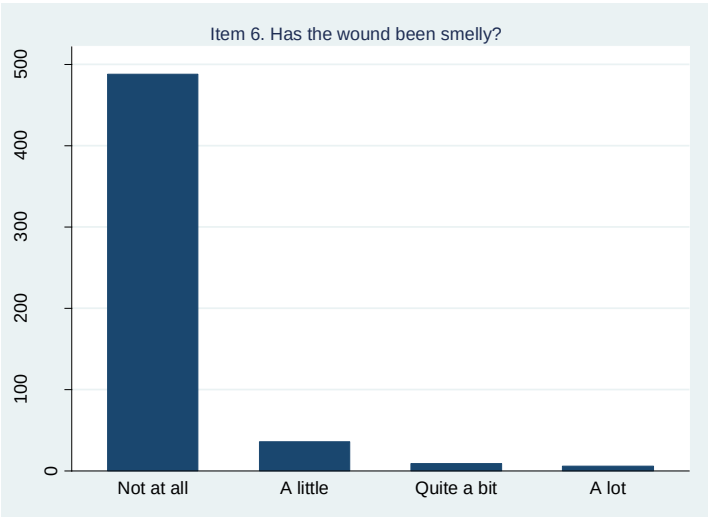


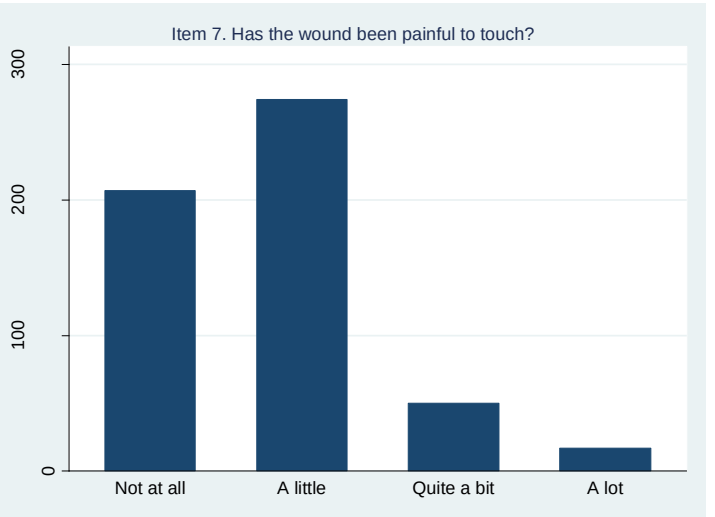

Item 4. Have the edges of any part of the wound separated/gaped open on their own accord? (spontaneous dehiscenc
0
100
200
300
400
Not at all
A little
Quite a bit
A lot


Sub-item 4a. Did the skin separate?
0
20
40
60
80
Not at all
A little
Quite a bit
A lot

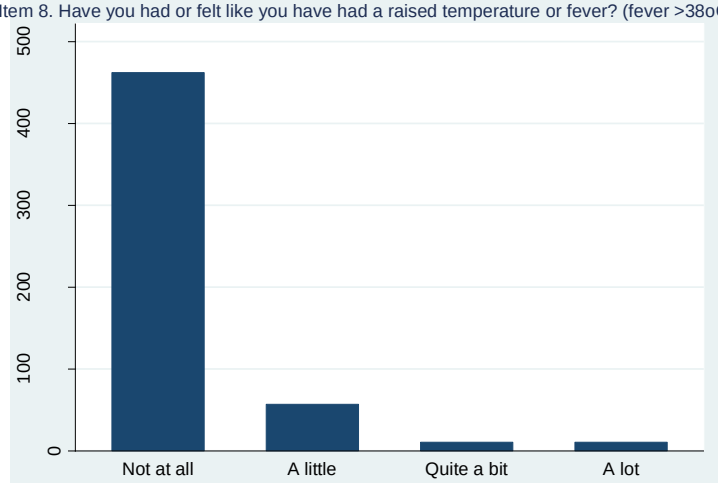

Sub-item 4b. Did the deeper tissue separate?
0
20
40
60
80
100
Not at all
A little
Quite a bit
A lot


Item 5. Has the area around the wound become swollen?
0
100
200
300
400
Not at all
A little
Quite a bit
A lot

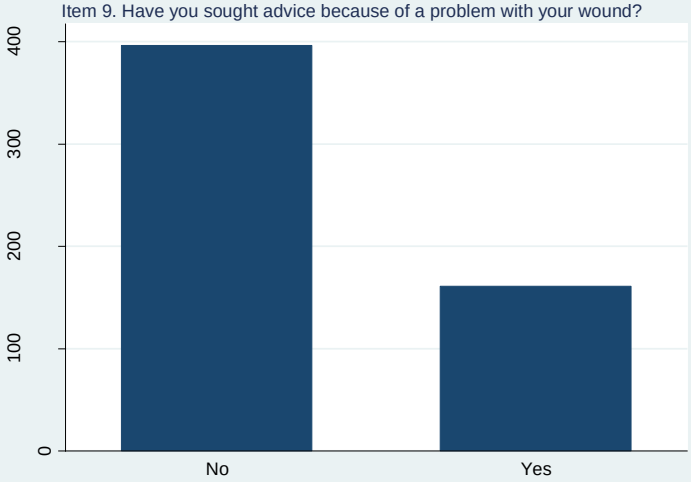

Item 6. Has the wound been smelly?
0
100
200
300
400
500
Not at all
A little
Quite a bit
A lot


Item 7. Has the wound been painful to touch?
0
100
200
300
Not at all
A little
Quite a bit
A lot

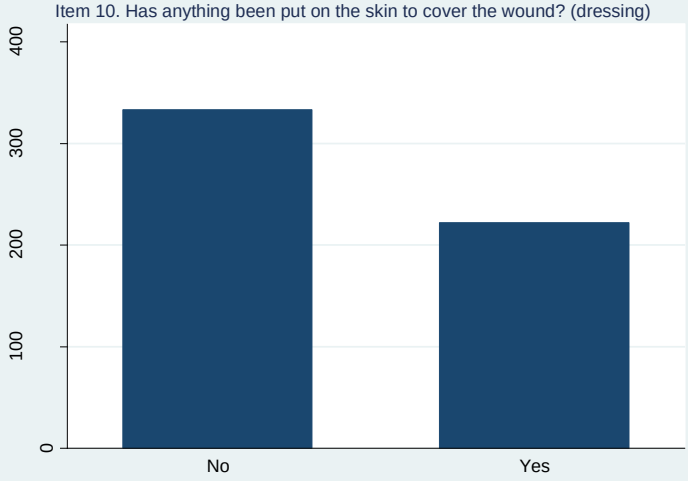
Item 8. Have you had or felt like you have had a raised temperature or fever? (fever >38oC)



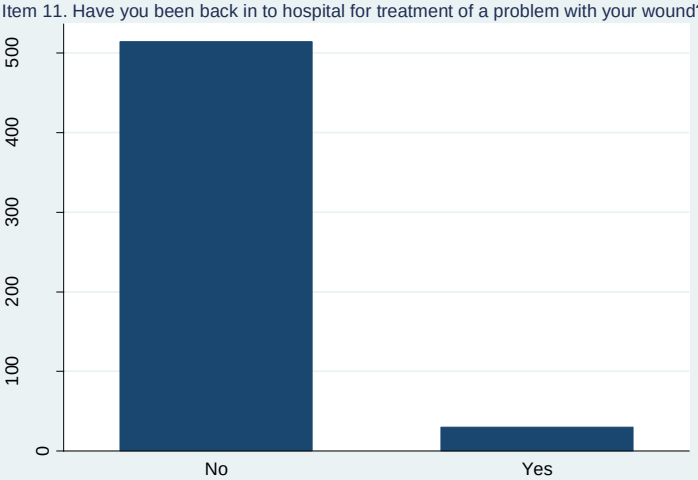
Item 9. Have you sought advice because of a problem with your wound?



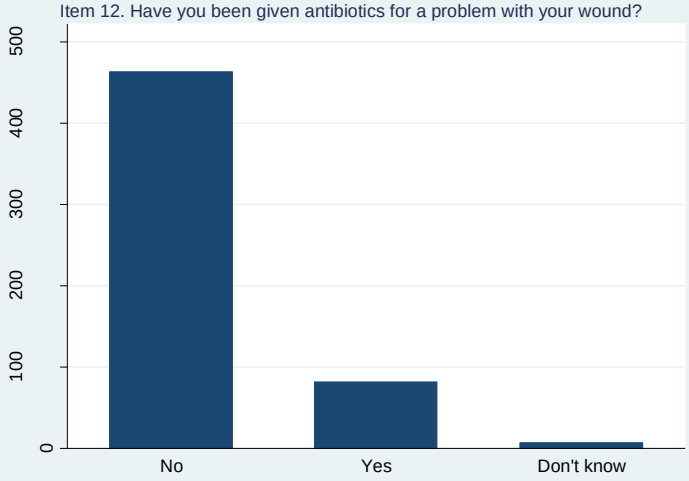
Item 10. Has anything been put on the skin to cover the wound? (dressing)



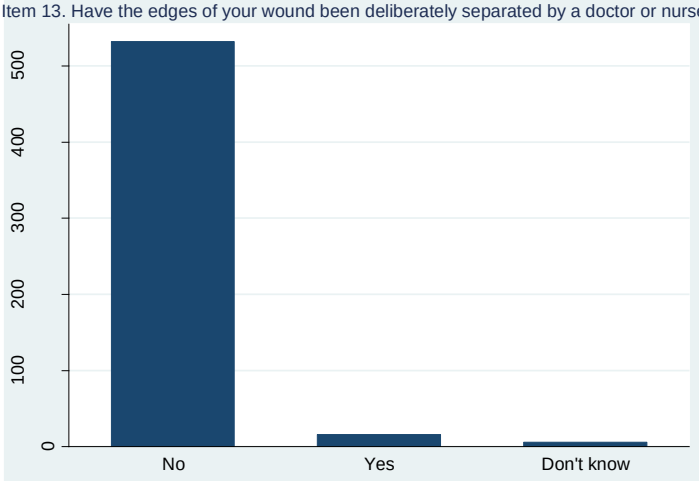
Item 11. Have you been back in to hospital for treatment of a problem with your wound?

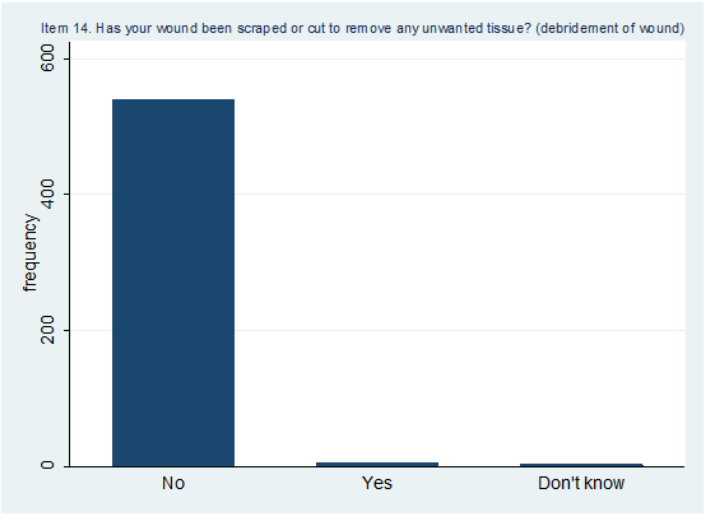


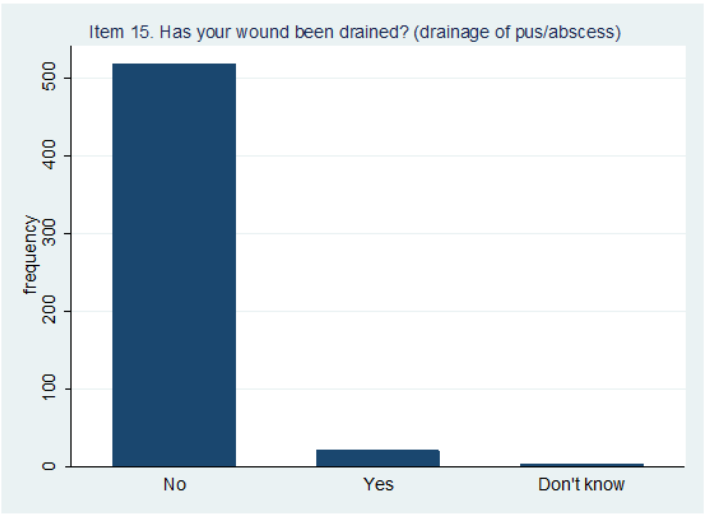
Item 12. Have you been given antibiotics for a problem with your wound?

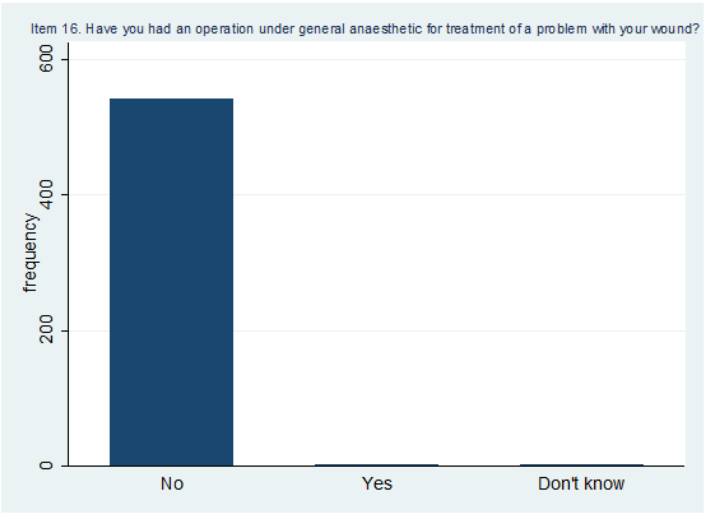


Item 13. Have the edges of your wound been deliberately separated by a doctor or nurse?




Item 14. Has your wound been scraped or cut to remove any unwanted tissue? (debridement of wound)
frequency
0
200
400
600
No
Yes
Don't know


Item 15. Has your wound been drained? (drainage of pus/abscess)
frequency
0
100
200
300
400
500
No
Yes
Don't know


Item 16. Have you had an operation under general anaesthetic for treatment of a problem with your wound?
frequency
0
200
400
600
No
Yes
Don't know

Appendix 19. Item-to-item correlation matrix for responses in participant self-assessments (cohort study data)

Item	Q1	Q2	Q3	Q3a	Q3b	Q3c	Q4	Q4a	Q4b	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14	Q15	Q16
Q1	1																				
Q2	0.53	1																			
Q3	0.34	0.26	1																		
Q3a	0.15	0.13	0.60	1																	
Q3b	0.33	0.26	0.81	0.33	1																
Q3c	0.29	0.14	0.56	0.17	0.27	1															
Q4	0.28	0.22	0.53	0.25	0.47	0.49	1														
Q4a	0.28	0.21	0.53	0.29	0.49	0.49	0.94	1													
Q4b	0.19	0.13	0.39	0.23	0.43	0.22	0.66	0.73	1												
Q5	0.25	0.27	0.11	0.15	0.10	0.06	0.14	0.16	0.12	1											
Q6	0.19	0.16	0.31	0.21	0.27	0.30	0.23	0.24	0.23	0.09	1										
Q7	0.24	0.27	0.07	0.07	0.07	0.10	0.10	0.14	0.06	0.31	0.26	1									
Q8	0.16	0.24	0.21	0.20	0.23	0.08	0.25	0.27	0.27	0.13	0.27	0.08	1								
Q9	0.27	0.22	0.50	0.39	0.42	0.31	0.40	0.41	0.29	0.19	0.21	0.18	0.21	1							
Q10	0.16	0.12	0.41	0.31	0.33	0.25	0.23	0.24	0.17	0.01	0.08	-0.05	0.07	0.30	1						
Q11	0.27	0.04	0.42	0.15	0.35	0.31	0.32	0.33	0.36	0.15	0.11	0.00	0.27	0.36	0.17	1					
Q12	0.42	0.27	0.51	0.28	0.46	0.45	0.35	0.35	0.18	0.11	0.11	0.04	0.24	0.47	0.30	0.50	1				
Q13	0.16	0.12	0.26	0.18	0.28	0.14	0.22	0.23	0.39	0.09	0.17	0.07	0.15	0.17	0.15	0.23	0.21	1			
Q14	0.13	-0.05	0.12	0.09	0.15	0.07	0.04	0.04	0.04	0.01	-0.03	0.04	-0.04	0.18	0.11	0.21	0.15	0.15	1		
Q15	0.17	0.04	0.33	0.20	0.28	0.27	0.19	0.13	0.21	0.02	0.19	0.01	0.09	0.18	0.17	0.31	0.37	0.38	0.12	1	
Q16	0.06	0.00	0.04	0.20	0.08	-0.02	0.03	0.03	-0.02	0.19	-0.02	-0.03	-0.03	0.13	0.07	-0.02	-0.03	-0.02	-0.01	-0.01	1

Values are Pearson correlation coefficient (Pearson's r)

Appendix 20. Multi-trait scaling: item-scale correlations for a hypothesised set of multiple scales and single items (cohort study data, participant self-assessments)

		Patient self-assessment n=284					
		Scale 1 (Inflammation)	**Scale 2 (Wound leaking)**	**Scale 3 (Wound care interventions)**	**Scale 4 (Dehiscence)**	**Single item (Smell)**	**Single item (Fever)**
Number of items in scale		4	5	7	2	1	1
Cronbach alpha co-efficient		0.62	0.70	0.64	0.75	-	-
Item		**Item-scale correlation**					
1	Was there redness spreading away from the wound? (erythema/cellulitis)	0.42*	0.32	0.40	0.31	0.17	0.14
2	Was the area around the wound warmer than the surrounding skin?	0.47*	0.24	0.22	0.23	0.13	0.24
5	Has the area around the wound become swollen?	0.35*	0.08	0.20	0.14	0.07	0.11
7	Has the wound been painful to touch?	0.35*	-0.00	0.12	0.11	0.24	0.07
3	Was any part of the wound leaking fluid?	0.25	0.73*	0.65	0.56	0.31	0.21
3a	Was it clear fluid? (serous exudate)	0.19	0.54*	0.41	0.29	0.22	0.20
3b	Was it blood-stained fluid? (haemoserous exudate)	0.24	0.67*	0.56	0.52	0.26	0.24
3c	Was it thick and yellow/green fluid (pus/purulent exudate)	0.19	0.50*	0.45	0.48	0.30	0.06
10	Has anything been put on the skin to cover the wound? (dressing)	0.12	0.43*	0.37	0.26	0.11	0.09

9	Have you sought advice because of a problem with your wound, other than at a routine planned follow-up appointment?	0.33	0.51	0.44*	0.41	0.22	0.22
11	Have you been back into hospital for treatment with a problem with your wound?	0.14	0.37	0.51*	0.35	0.10	0.26
12	Have you been given antibiotics for a problem with you wound?	0.29	0.51	0.55*	0.34	0.11	0.23
13	Have the edges of your wound been deliberately separated by a doctor or nurse?	0.16	0.27	0.33*	0.31	0.17	0.16
14	Has your wound been scraped or cut to remove any unwanted tissue? (debridement of wound)	0.08	0.12	0.24*	0.06	-0.03	-0.04
15	Has your wound been drained? (drainage of pus/abscess)	0.09	0.28	0.39*	0.26	0.21	0.09
16	Have you had an operation under general anaesthetic for treatment of a problem with your wound?	0.08	0.09	0.05*	0.00	-0.02	-0.03
4	Have the edges of any part of the wound separated/gaped open on their own accord? (spontaneous dehiscence)	0.27	0.52	0.46	0.66*	0.22	0.25
4b	Did the deeper tissue separate?	0.16	0.40	0.39	0.66*	0.22	0.26
6	Has the wound been smelly?	0.23	0.25	0.23	0.23	*	0.27
8	Have you had, or felt like you have had, a raised temperature or fever? (fever >38^{o}C)	0.19	0.20	0.26	0.26	0.27	*

*Indicates item-scale correlation with hypothesised scale

Appendix 21. Multi-trait scaling: item-scale correlations for a hypothesised set of multiple scales and single items (cohort study data, HCP observer assessments)

		HCP observer assessment n=307					
		Scale 1 (Inflammation)	**Scale 2 (Wound leaking)**	**Scale 3 (Wound care interventions)**	**Scale 4 (Dehiscence)**	**Single item (Smell)**	**Single item (Fever)**
Number of items in scale		4	5	7	2	1	1
Cronbach alpha co-efficient		0.72	0.70	0.66	0.79	-	-
Item		**Item-scale correlation**					
1	Was there redness spreading away from the wound? (erythema/cellulitis)	0.63*	0.48	0.43.	0.37	0.24	0.26
2	Was the area around the wound warmer than the surrounding skin?	0.61*	0.40	0.38	0.38	0.23	0.35
5	Has the area around the wound become swollen?	0.46*	0.22	0.27	0.22	0.23	0.25
7	Has the wound been painful to touch?	0.35*	0.25	0.18	0.24	0.16	0.11
3	Was any part of the wound leaking fluid?	0.45	0.78*	0.59	0.55	0.30	0.25
3a	Was it clear fluid? (serous exudate)	0.18	0.35*	0.21	0.25	0.17	0.06
3b	Was it blood-stained fluid? (haemoserous exudate)	0.40	0.54*	0.45	0.43	0.27	0.31
3c	Was it thick and yellow/green fluid (pus/purulent exudate)	0.51	0.45*	0.47	0.45	0.33	0.24
10	Has anything been put on the skin to cover the wound? (dressing)	0.28	0.48*	0.44	0.30	0.23	0.21
9	Have you sought advice because of a problem with your wound, other than at a routine planned follow-up appointment?	0.38	0.51	0.52*	0.38	0.28	0.24
11	Have you been back into hospital for treatment with a problem with your wound?	0.09	0.31	0.49*	0.30	0.14	0.44

12	Have you been given antibiotics for a problem with you wound?	0.48	0.51	0.57*	0.39	0.21	0.34
13	Have the edges of your wound been deliberately separated by a doctor or nurse?	0.19	0.33	0.37*	0.38	0.22	0.31
14	Has your wound been scraped or cut to remove any unwanted tissue? (debridement of wound)	0.17	0.15	0.12*	0.27	0.15	0.30
15	Has your wound been drained? (drainage of pus/abscess)	0.13	0.21	0.41*	0.22	0.08	0.10
16†	Have you had an operation under general anaesthetic for treatment of a problem with your wound?	-	-	-	-	-	-
4	Have the edges of any part of the wound separated/gaped open on their own accord? (spontaneous dehiscence)	0.42	0.55	0.54	0.73*	0.33	0.34
4b	Did the deeper tissue separate?	0.26	0.36	0.36	0.73*	0.11	0.29
6	Has the wound been smelly?	0.29	0.34	0.31	0.31	*	0.24
8	Have you had, or felt like you have had, a raised temperature or fever? (fever >38^{o}C)	0.32	0.29	0.43	0.37	0.24	*

*Indicates item-scale correlation with hypothesised scale

† Results exclude this item from the analysis because all observer assessment scores were equal to zero

Appendix 22. Factor loadings for a three-factor model, ml method of estimation, unrotated (cohort study data, participant self-assessments)

		Participant self-assessment (n=201)		
		Factor 1	**Factor 2**	**Factor 3**
	Eigenvalue	3.92	1.79	0.96
	Item	**Item-factor loading**	**Item-factor loading**	**Item-factor loading**
1	Was there redness spreading away from the wound? (erythema/cellulitis)	0.2896	0.4564	0.0724
2	Was the area around the wound warmer than the surrounding skin?	0.1267	0.2983	0.2885
3	Was any part of the wound leaking fluid?	1.0000	-0.0000	-0.0000
3a	Was it clear fluid? (serous exudate)	0.5465	-0.0046	0.1192
3b	Was it blood-stained fluid? (haemoserous exudate)	0.7366	0.1735	0.0138
3c	Was it thick and yellow/green fluid (pus/purulent exudate)	0.4877	-0.0211	-0.0024
4	Have the edges of any part of the wound separated/gaped open on their own accord? (spontaneous dehiscence)	0.4973	0.1807	0.2473
4b	Did the deeper tissue separate?	0.3748	0.3580	0.3553
5	Has the area around the wound become swollen?	0.0651	0.3232	0.1771
6	Has the wound been smelly?	0.3911	0.1349	0.2796
7	Has the wound been painful to touch?	0.1542	0.3286	0.3021
8	Have you had, or felt like you have had, a raised temperature or fever? (fever >38^{o}C)	0.1896	0.2455	0.1583
9	Have you sought advice because of a problem with your wound, other than at a routine planned follow-up appointment?	0.5082	0.2573	-0.0303
10	Has anything been put on the skin to cover the wound? (dressing)	0.3780	0.1142	-0.0231
11	Have you been back into hospital for treatment with a problem with your wound?	0.4123	0.4572	-0.4323
12	Have you been given antibiotics for a problem with you wound?	0.5387	0.4339	-0.2726
13	Have the edges of your wound been deliberately separated by a doctor or nurse?	0.2675	0.4832	0.2198
14	Has your wound been scraped or cut to remove any unwanted tissue? (debridement of wound)	0.1929	0.4096	-0.3493
15	Has your wound been drained? (drainage of pus/abscess)	0.4123	0.3658	0.1087
16†	Have you had an operation under general anaesthetic for treatment of a problem with your wound?	-	-	-

† Model dropped this item because of collinearity

Appendix 23. Factor loadings for a three-factor model, ml method of estimation, unrotated (cohort study data, HCP observer assessments)

		HCP assessment (n=290)		
		Factor 1	**Factor 2**	**Factor 3**
	Eigenvalue	4.06	2.01	1.03
	Item	**Item-factor loading**	**Item-factor loading**	**Item-factor loading**
1	Was there redness spreading away from the wound? (erythema/cellulitis)	0.7953	0.5143	-0.4552
2	Was the area around the wound warmer than the surrounding skin?	0.3657	0.6071	-0.3791
3	Was any part of the wound leaking fluid?	1.0000	-0.0000	-0.0000
3a	Was it clear fluid? (serous exudate)	0.5664	-0.1378	0.0327
3b	Was it blood-stained fluid? (haemoserous exudate)	0.6646	0.0852	-0.0489
3c	Was it thick and yellow/green fluid (pus/purulent exudate)	0.5951	0.3056	-0.0995
4	Have the edges of any part of the wound separated/gaped open on their own accord? (spontaneous dehiscence)	0.5481	0.5348	0.4237
4b	Did the deeper tissue separate?	0.3683	0.4743	0.4818
5	Has the area around the wound become swollen?	0.1792	0.3324	-0.2812
6	Has the wound been smelly?	0.2689	0.1619	0.0061
7	Has the wound been painful to touch?	0.2364	0.2194	-0.1311
8	Have you had, or felt like you have had, a raised temperature or fever? (fever >38^{o}C)	0.2461	0.3673	0.1335
9	Have you sought advice because of a problem with your wound, other than at a routine planned follow-up appointment?	0.4418	0.3285	-0.0030
10	Has anything been put on the skin to cover the wound? (dressing)	0.4716	0.1414	-0.0060
11	Have you been back into hospital for treatment with a problem with your wound?	0.2559	0.1930	0.2606
12	Have you been given antibiotics for a problem with you wound?	0.4910	0.4223	-0.0412
13	Have the edges of your wound been deliberately separated by a doctor or nurse?	0.3593	0.1417	0.1633
14	Has your wound been scraped or cut to remove any unwanted tissue? (debridement of wound)	0.0058	0.0710	0.1618
15	Has your wound been drained? (drainage of pus/abscess)	0.2232	0.2429	0.1423
16†	Have you had an operation under general anaesthetic for treatment of a problem with your wound?	-	-	-

† Model dropped this item because of collinearity

Appendix 24. Factor loadings for a single factor model, ml method of estimation (pilot RCT data)

		Participant self-assessment (n=161)	HCP assessment (n=211)
		Factor 1	**Factor 1**
	Eigenvalue	6.43	5.07
	Item*	**Item-factor loading**	**Item-factor loading**
3	Was any part of the wound leaking fluid?	0.8636	0.9299
4	Have the edges of any part of the wound separated/gaped open on their own accord? (spontaneous dehiscence)	0.8425	0.4112
4b**	Did the deeper tissue separate?	0.7517	-
3c	Was it thick and yellow/green fluid (pus/purulent exudate)	0.7096	0.7118
3b	Was it blood-stained fluid? (haemoserous exudate)	0.6816	0.3994
12	Have you been given antibiotics for a problem with you wound?	0.6696	0.6648
3a	Was it clear fluid? (serous exudate)	0.6070	0.5172
9	Have you sought advice because of a problem with your wound, other than at a routine planned follow-up appointment?	0.6060	0.5042
6	Has the wound been smelly?	0.5662	0.5885
8	Have you had, or felt like you have had, a raised temperature or fever? (fever >38^{o}C)	0.5566	0.3571
5	Has the area around the wound become swollen?	0.5067	0.4525
1	Was there redness spreading away from the wound? (erythema/cellulitis)	0.4811	0.6664
14	Has your wound been scraped or cut to remove any unwanted tissue? (debridement of wound)	0.4578	-0.0036
10	Has anything been put on the skin to cover the wound? (dressing)	0.4545	0.5238
7	Has the wound been painful to touch?	0.4448	0.4765
13	Have the edges of your wound been deliberately separated by a doctor or nurse?	0.4334	0.4798
2	Was the area around the wound warmer than the surrounding skin?	0.4117	0.5708
11	Have you been back into hospital for treatment with a problem with your wound?	0.4044	0.2865
15	Has your wound been drained? (drainage of pus/abscess)	0.0856	0.3835
16†	Have you had an operation under general anaesthetic for treatment of a problem with your wound?	-	-

*Items are ordered in ascending values for participant self-assessment item-factor loading
**Model dropped this item because of zero variance
† Model dropped this item because of collinearity

Appendix 25. Polychoric matrix of item-to-item correlations for responses in participant self-assessments (combined cohort and pilot RCT data)

Item	Q1	Q2	Q3	Q3a	Q3b	Q3c	Q4	Q4a	Q4b	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14	Q15	Q16
Q1	1																				
Q2	0.63	1																			
Q3	0.51	0.28	1																		
Q3a	0.40	0.21	0.84	1																	
Q3b	0.46	0.30	0.90	0.61	1																
Q3c	0.45	0.28	0.83	0.62	0.57	1															
Q4	0.46	0.35	0.74	0.57	0.64	0.74	1														
Q4a	0.47	0.35	0.77	0.61	0.68	0.74	0.99	1													
Q4b	0.58	0.48	0.79	0.51	0.73	0.62	0.91	0.93	1												
Q5	0.41	0.48	0.28	0.29	0.35	0.27	0.41	0.40	0.52	1											
Q6	0.44	0.19	0.64	0.44	0.56	0.61	0.55	0.54	0.61	0.25	1										
Q7	0.42	0.49	0.35	0.38	0.34	0.35	0.34	0.35	0.58	0.56	0.46	1									
Q8	0.29	0.46	0.38	0.31	0.44	0.34	0.49	0.48	0.56	0.33	0.52	0.31	1								
Q9	0.46	0.35	0.77	0.74	0.69	0.63	0.61	0.65	0.58	0.32	0.55	0.50	0.42	1							
Q10	0.20	0.17	0.62	0.47	0.61	0.56	0.40	0.41	0.50	0.11	0.24	0.17	0.23	0.50	1						
Q11	0.42	0.18	0.65	0.35	0.65	0.42	0.49	0.48	0.66	0.31	0.36	0.20	0.47	0.65	0.52	1					
Q12	0.61	0.45	0.77	0.58	0.67	0.78	0.71	0.71	0.68	0.38	0.57	0.35	0.45	0.81	0.57	0.80	1				
Q13	0.57	0.49	0.63	0.40	0.72	0.10	0.49	0.58	0.77	0.43	0.55	0.36	0.42	0.54	0.64	0.58	0.58	1			
Q14	0.78	0.10	0.73	0.22	0.81	.	0.56	0.56	0.75	0.42	0.42	0.53	0.34	.	.	.	.	0.82	1		
Q15	0.28	0.19	0.70	0.53	0.61	0.43	0.45	0.43	0.58	0.11	0.40	0.13	0.46	0.44	0.56	0.53	0.60	0.81	0.55	1	
Q16	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	1

Appendix 26. Polychoric matrix factor loadings for a single factor model, ml method of estimation (combined cohort and pilot RCT data)

		Participant self-assessment (n=364)	HCP assessment (n=505)
		Factor 1	**Factor 1**
	Eigenvalue	6.83	6.35
	Item*	**Item-factor loading**	**Item-factor loading**
12	Have you been given antibiotics for a problem with you wound?	0.9224	0.8901
9†	Have you sought advice because of a problem with your wound, other than at a routine planned follow-up appointment?	0.8548	-
3b	Was it blood-stained fluid? (haemoserous exudate)	0.7893	0.6344
4	Have the edges of any part of the wound separated/gaped open on their own accord? (spontaneous dehiscence)	0.7692	0.7390
3c	Was it thick and yellow/green fluid (pus/purulent exudate)	0.7618	0.8093
11†	Have you been back into hospital for treatment with a problem with your wound?	0.7382	-
3a	Was it clear fluid? (serous exudate)	0.7005	0.5037
6	Has the wound been smelly?	0.6447	0.6288
15	Has your wound been drained? (drainage of pus/abscess)	0.6263	0.6802
1	Was there redness spreading away from the wound? (erythema/cellulitis)	0.6109	0.7871
10	Has anything been put on the skin to cover the wound? (dressing)	0.6020	0.7159
8	Have you had, or felt like you have had, a raised temperature or fever? (fever >38^{o}C)	0.5365	0.5778
7	Has the wound been painful to touch?	0.4576	0.4174
2	Was the area around the wound warmer than the surrounding skin?	0.4486	0.7188
5	Has the area around the wound become swollen?	0.4237	0.5024
3†	Was any part of the wound leaking fluid?	-	-
4b†	Did the deeper tissue separate?	-	-
13†	Have the edges of your wound been deliberately separated by a doctor or nurse?	-	0.6617
14**	Has your wound been scraped or cut to remove any unwanted tissue? (debridement of wound)	-	-
16**	Have you had an operation under general anaesthetic for treatment of a problem with your wound?	-	-

*Items are ordered in ascending values for item-factor loading

**Item excluded because too few observations for a polychoric matrix

† Where data is absent, model dropped this item because of collinearity

Appendix 27. Final version of the SSI measure for use in future studies

Wound Healing Questionnaire

We are interested in knowing how your wound(s) have healed since you left hospital after having surgery. Please complete this short questionnaire yourself. It is fine to ask someone else to write the answers for you or help answer some of the questions, for example if you have not been able to see your wound(s).

If you have more than one wound, please answer the questions **thinking about just one wound** — either your main wound or another wound if there have been any concerns about how it has been healing. We would like you to think about the wounds on your skin rather than any wounds that may be inside your body.

The following questions ask about how your wound has healed and wound care **since you left hospital after having surgery**. It includes some problems that may occur with wound healing. Please note these are only possibilities and do not occur for many people. The words in brackets are the medical terminology. Next to each question, please tick the box that is most relevant to your experience.

Since you left hospital after having surgery....

	Not at all	A little	Quite a bit	A lot
1. Was there redness spreading away from the wound? (erythema/cellulitis)	☐	☐	☐	☐
2. Was the area around the wound warmer than the surrounding skin?	☐	☐	☐	☐
3. Has any part of the wound leaked clear fluid? (serous exudate)	☐	☐	☐	☐
4. Has any part of the wound leaked blood-stained fluid? (haemoserous exudate)	☐	☐	☐	☐
5. Has any part of the wound leaked thick and yellow/green fluid? (pus/purulent exudate)	☐	☐	☐	☐
6a. Have the edges of any part of the wound separated/gaped open on their own accord? (spontaneous dehiscence)	☐	☐	☐	☐
Please answer the next question only if you have said the edges of the wound separated/gaped open:				
6b. Did the deeper tissue also separate?	☐	☐	☐	☐
7. Has the area around the wound become swollen?	☐	☐	☐	☐
8. Has the wound been smelly?	☐	☐	☐	☐
9. Has the wound been painful to touch?	☐	☐	☐	☐
10. Have you had, or felt like you have had, a raised temperature or fever (fever >38°C)	☐	☐	☐	☐

	Yes	No
11. Have you sought advice because of a problem with your wound, other than at a planned follow-up appointment?	☐	☐
12. Has anything been put on the skin to cover the wound? (dressing)	☐	☐
13. Have you been back into hospital for treatment of a problem with your wound?	☐	☐
14. Have you been given antibiotics for a problem with your wound?	☐	☐
15. Have the edges of your wound been deliberately separated by a doctor or nurse?	☐	☐
16. Has your wound been scraped or cut to remove any unwanted tissue? (debridement of wound)	☐	☐
17. Has your wound been drained? (drainage of pus / abscess)	☐	☐
18. Have you had an operation under general anaesthetic for treatment of a problem with your wound?	☐	☐

Participant Informatio
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- Any information
  confidential
- Ask us if there is
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Summary

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testing phase (Study 2; Phase 1)

During the visit, you will be asked to follow some written instructions to take a photograph of your wound using the camera on your own mobile phone or tablet computer. The photograph will be a close up of your wound and you should not be identifiable from it (for example, it should not include your face). The photograph can be taken privately (in a different room to the researcher) if you wish. If you need help from a partner or friend to take the photograph that is fine. The researcher will then ask you about how easy or difficult it was to follow the instructions and ask your thoughts on how they could be improved. The researcher will take notes, and if you are happy, will audio-record your conversations.

You will then be asked to send your digital photograph to the research team. This is done via an online system which is completely secure and confidential. The researcher will arrange for an email to be sent to you so that you can login to the system (on a secure study database held at the University of Bristol). You will be asked to follow instructions to 'upload' your wound photograph. The researcher will sit with you and talk to you as you do this, to see whether any problems occur or if any of the instructions need improving. You can then delete the photograph from your own phone or camera whenever you like.

After uploading your photograph you will be asked to complete a short online questionnaire about how your wound has been healing and talk to the researcher about your answers.

The researcher will collect some basic information about you (e.g. your age, how much you use your camera), and your wound (e.g. what type of surgery you had, where your wound is).

5 What are the possible benefits of taking part?

We hope that you will enjoy helping us to develop, refine and test this process, which aims to improve how wounds can be monitored after people leave hospital.

6 Are there any risks and disadvantages?

We do not think there will be any risks or disadvantages to taking part in this study, other than setting aside some of your own time.

Taking part in this study will not affect the normal care or treatment you get from your doctors and nurses. The study is just interested in finding out whether is possible to obtain clear digital photographs of wounds from people after they have left hospital.

7 What will happen to the information I provide?

The information you provide will be used to help develop, test and evaluate the process of whether it is possible for people to take a clear photograph of their own wound and send it to the research team after they have left hospital.

How will my information be stored?

All information we collect in this study will be stored securely at the University of Bristol and in accordance with the UK Data Protection Act. At the end of the study the information including wound photographs that has been collected will be stored within the University of Bristol Research Data Storage Facility (RDSF), which a safe and secure location.

Will my information be shared with anyone else?

We may use quotes and photographs that you have provided when writing up the study for reports, publications or in presentations. These would be anonymised (meaning the removal of any information so that you could not be identified). You have the right to ask us not to use your quotes or photographs if you prefer.

The University of Bristol is committed to sharing its research. We ask that you will be willing for your anonymised data to be shared with other professionals and used to support other research in future. Only anonymised data would ever be shared; all identifying data would be removed so that no one will be able to trace it back to you.

8 How will my information be kept confidential

Any information you provide to us will be treated as confidential.

All data (including information about you, your wound and your photograph) will be labelled with a number (study participant number) that is unique to you. This will be stored separately from your personal information such as your name and address.

All data will be keep on University of Bristol computers that can only be accessed by authorised members of the study team with a password.

The photograph we ask you to take will be a close up of your wound and you should not be identifiable from it. The system that we will use for you to send in your photograph is a web-based application designed for collecting data for research studies. This is a secure way of collecting and storing data held on the University of Bristol computer server and is only accessible by authorised members of the study team. You can delete the photograph from your own phone or camera whenever you like.

9 What will happen to the results of this study?

The findings from this study will help inform us whether this method for collecting self-taken images of the wound after leaving hospital is possible.

We plan to publish the result of this study in a peer-reviewed, open-access academic journal. This means that the study will have been reviewed by other professionals, and after publication it will be freely available for anyone to read. We intend to present the findings to other researchers, academics and healthcare professionals at local, national and international conferences and scientific meetings. We will also look for opportunities to present to work to the public and other patients.

10 Who is organising and funding this study?

Researchers at the University of Bristol are running this study. The study is being undertaken as part of an academic degree (PhD). The work is supported by the Medical Research Council (MRC) Network of Hubs for Trials Methodology Research and the National Institute for Health Research Bristol Biomedical Research Centre (NIHR BRC Bristol). *The study has XXX NHS ethical approval.*

11 What if something goes wrong?

If you have any concerns or questions about this study please contact us on 0117 928

7367. For independent advice or to make a complaint, you can contact *[insert local address/telephone/email for University Hospitals Bristol NHS Foundation Trust*	*Patient Support and Complaints Team, or North Bristol NHS Trust Advice & Complaints Team]*

Thank you taking the time to read this information.

Appendix 29. Consent form for the Selfi wound study (Study 2; Phases 1 & 2)

IRAS ID: IRAS ID 239186
Trust study number:
REC No:
<<<Insert PI name>>
<<Insert PI address>>
<<Insert PI tel number>>

Trust logo or replace with <*To be printed on site headed paper*>

Participant ID for this study

The Selfi wound study

Self-taken **i**mages of surgical wounds

Consent Form (for study Phase A and B)

Please ask the participant to complete the following:

Participant to initial:

		Initials
1.	I confirm that I have read and understood the information leaflet (dated ____/____/____, version _____)	
2.	I have had the opportunity to consider the information, ask questions about the study and have had these answered satisfactory.	
3.	I understand that my participation is voluntary and that I am free to withdraw from the study at any time without giving a reason, and that withdrawing from the study will not affect my medical care or legal rights	
4.	I give permission for relevant sections of my medical records to be looked at by the study team, the regulatory authorities or the hospital trust overseeing the research. I understand that strict confidentiality will be maintained.	
5.	I give permission for data that I have provided, including photographs of my wound and any interview quotes to be used in reports, publications and presentations of the study findings. I understand that these data will be anonymised and I will not be identifiable.	
6.	I agree to my data (including my wound photograph and any audio-recorded interviews) being transferred to, and retained by, the University of Bristol for training, teaching and research purposes, now and in the future.	
7.	I understand that the information collected about me may be used to support other research in the future and may be shared anonymously with other researchers.	
8.	I agree to take part in this study, which involves providing a photo of my wound after surgery.	

Name of participant	Signature	Date
Name of person taking consent	Signature	Date

1 copy for participant; 1 for research team (original); 1 to be kept with hospital notes

Appendix 30. Prompt sheet to guide the Selfi wound study cognitive interviews (Study 2; Phase 1)

Opening

Interviewer will re-iterate study information, answer any questions, and take written consent. Permission to audio-record the interview will be sought.

Background, interviewee details and ice breaker

- Pre-defined, targeted questions
- Participant's background (age, education level, cohabitation and employment information) and details of surgical procedure they have had (type of procedure, planned or emergency, when, location and number of wounds, wound healing experience).
- Participant's experience and familiarity with technology (type of phone they use, tablet or other handheld device, details on the camera facility, whether they access the internet on their phone, tablet or other handheld device, use of camera facility on phone, tablet or other handheld device, frequency of use, confidence)
  e.g. "Do you ever use your phone to send or receive email?" "Do you ever use your phone to take pictures?"

Wound photography and image upload

- Interviewer will provide paper-copy instructions to the participant and ask them to read through and follow the instructions to take a photograph(s) of their wound. Interviewer will explain the 'think aloud' technique and ask them to verbalise their thoughts as they read and carry out the instructions. Protection of privacy and dignity will be re-iterated and participant/interviewer will move to another room if required.
- Interviewer will observe participant using mobile phone / tablet etc to access email and follow the link to log in to the REDCap database. Participant will be asked to follow the instructions and continue to 'think aloud'.
- Interviewer will follow-up on any observed or raised issues to explore problems or confusion further
  e.g. "You paused for a while as you were reading [*part of the instructions*]. Can you tell me what you were thinking?"

Debriefing

Pre-defined, targeted questions:

1. *Were there any parts of the wound photography instructions that you found confusing / difficult / problematic? If yes, which one? Why?*
2. *Were there any parts of the image upload process that you found confusing / difficult / problematic? If yes, which one? Why?*

3. *Do you have any suggestions for how the instructions could be improved?*
4. *Do you have a preference for receiving the link to access the study database and upload your photograph via email or text if used in future?*
5. *How did you find the experience of seeing your wound?*

Completion of Bluebelle wound healing questionnaire (WHQ)

Interviewer will provide a paper-copy of the WHQ and ask the participant to complete it on their own / with help from their carer. After completion, Interviewer will run through the responses

- Explore responses to items, elicit more information or elaboration to confirm/amend the patient's response

Closing

Researcher checks understanding of any outstanding points, answers further questions, and checks to see if participant would like to receive a summary of findings. Participant is thanked for taking part in the study.

University of BRISTOL

The Selfi wound study

Self-taken images of surgical wounds

Exploring the feasibility of a method for the collection of self/carer-taken images of p surgical wounds after leaving hospital

We invite you to take part in a study

- Before you decide whether to take part, please read the following information carefully. Discuss it with friends and relatives if you wish.
- You are free to choose whether or not to take part
- If you choose to take part, you may withdraw from the study at any time without giving a reason
- Any information you provide will be kept confidential
- Ask us if there is anything that is not clear or if you would like more information

Summary

The aim of this study is to see if it is possible for people to take a clear photograph of their wound after they have left hospital using their own digital camera (e.g. mobile phone or other mobile digital device like an iPad® or tablet computer).

This is a research study to see if this process is possible and, if so, whether it could be used in the future to help monitor how the wound is healing after people have left hospital.

We are inviting you to take part in this study to help test instructions for taking a clear photograph and sending it in to the research team, so we can make sure the process is accurate and easy to follow.

If you are interested in taking part, please continue to read this leaflet.

Contents

How to contact the study team

If you have any questions about t study, please talk to the study researcher:

Ms Rhiannon Macefield
Tel: 0117 928 7367
Email: r.macefield@bristol.ac.uk
Bristol Medical School,
University of Bristol, Canynge Hall, 39 Whatley Road, Bristol. BS8 2PS

1 Aims of the study

After having surgery, it is important to check that the wound is healing as it should.

We are interested in finding out whether it is possible for people to take a clear photograph of their own wound after they have left hospital. This could be a useful method to use in future for research studies and in everyday care, as a way to help monitor how the wound is healing and check for any potential problems.

We are doing this study to explore whether this process is possible. First, we need to develop and test some instructions for people to take a clear photograph of the wound using their own digital cameras. Secondly, we need to see if people can use the system to send the digital photograph to the research team. Finally, we need to see if the photographs are suitable for assessing how the wound is healing.

2 Why have I been invited to take part?

We need people to help us develop, refine and test the instructions for taking a clear photograph and sending the images in to the research team.

You have been invited to take part because you are about to have, or have recently had, surgery.

You have also told us that you own, or have access to, a digital camera.

3 Do I have to take part?

It is completely up to you to decide whether you want to take part in this study or not. You can ask us any questions to help you decide. It is a research study and is not part of your treatment follow up.

If you decide to take part and then later change your mind, that is fine.

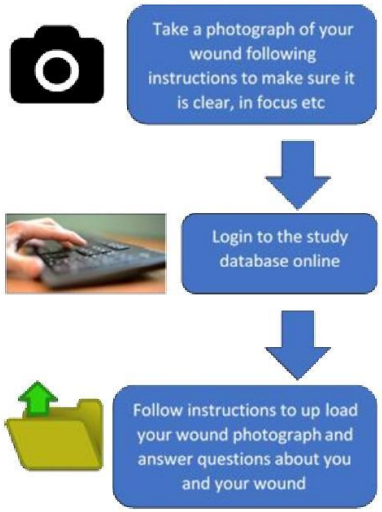
You can withdraw from the study at any time. If you have provided information (including information about you and your surgery, and any photographs of your wound you have sent us) and no longer wish us to use it, just let us know.

If you choose not to take part in this study your care will not be affected in any way.

4 What would taking part involve?

Taking part would involve you taking a photograph of your surgical wound after you have left hospital and sending it in to the research team. You will be given instructions on when and how to do this.

Overview of what you will be asked to do:



Appendix 31. Participant information leaflet for the Selfi wound study evaluation phase (Study 2; Phase 2)

If you decide to take part, you will be posted some instructions on how to take a clear photograph of your wound. The photograph will be a close up of your wound and you should not be identifiable from it (for example, it should not include your face). We would like you to follow the instructions to take a photograph using the camera on your own mobile phone or tablet device. If you need help from a partner or friend to take the photograph that is fine.

You will be sent an email from the research team to ask you to send in your digital photograph(s). The email will include a link to an online system which is completely secure and confidential (secure study database held at the University of Bristol). You will be asked to follow instructions to login to the system and 'upload' your wound photograph(s). You can then delete the photograph from your own phone or camera whenever you like. The research team will send you a reminder email if they have not received your photos within a week after sending the email, or will telephone you to check whether there have been any problems.

As well as uploading you photograph you will be asked to complete a short online questionnaire and provide some basic information about you (e.g. your age, how much you use your camera) and how your wound has been healing, and to give some feedback about how easy or difficult it was to take and upload the photograph(s).

After sending in your information, the researcher may telephone you to get a bit more feedback about how easy or difficult you found the whole process of taking and uploading your photograph(s). Not everyone will be telephoned. You can ask the researcher to call back on a day and time that suits you.

5 What are the possible benefits of taking part?

We hope that you will enjoy helping us to develop, refine and test this process, which aims to improve how wounds can be monitored after people leave hospital.

6 Are there any risks and disadvantages?

We do not think there will be any risks or disadvantages to taking part in this study, other than setting aside some of your own time.

Taking part in this study will not affect the normal care or treatment you get from your doctors and nurses. The study is not linked to your follow up care. **Your clinical care team will not see the photos and the photos will not be examined to assess how your wound is healing**. The study is just interested in finding out whether is possible to obtain clear digital photographs of wounds from people after they have left hospital. If you do have any wound healing problems, it is important that you contact your care team as normal.

7 What will happen to the information I provide?

The information you provide will be used to help develop, test and evaluate the process of whether it is possible for people to take a clear photograph of their own wound and send it to the research team after they have left hospital.

How will my information be stored?

All information we collect in this study will be stored securely at the University of Bristol and in accordance with the UK Data Protection Act. At the end of the study the information including wound photographs

that has been collected will be stored within the University of Bristol Research Data Storage Facility (RDSF), which a safe and secure location.

Will my information be shared with anyone else?

We may use quotes and photographs that you have provided when writing up the study for reports, publications or in presentations. These would be anonymised (meaning the removal of any information so that you could not be identified). You have the right to ask us not to use your quotes or photographs if you prefer.

The University of Bristol is committed to sharing its research. We ask that you will be willing for your anonymised data to be shared with other professionals and used to support other research in future. Only anonymised data would ever be shared; all identifying data would be removed so that no one will be able to trace it back to you.

8 How will my information be kept confidential

Any information you provide to us will be treated as confidential.

All data (including information about you, your wound and your photograph) will be labelled with a number (study participant number) that is unique to you. This will be stored separately from your personal information such as your name and address.

All data will be keep on University of Bristol computers that can only be accessed by authorised members of the study team with a password.

The photograph we ask you to take will be a close up of your wound and you should not be identifiable from it. The system that we will use for you to send in your photograph is a web-based application designed for collecting data for research studies. This is a secure way of collecting and storing data held on the University of Bristol computer server and is only accessible by authorised members of the study team. You can delete the photograph from your own phone or camera whenever you like.

9 What will happen to the results of this study?

The findings from this study will help inform us whether this method for collecting self-taken images of the wound after leaving hospital is possible.

We plan to publish the result of this study in a peer-reviewed, open-access academic journal. This means that the study will have been reviewed by other professionals, and after publication it will be freely available for anyone to read. We intend to present the findings to other researchers, academics and healthcare professionals at local, national and international conferences and scientific meetings. We will also look for opportunities to present to work to the public and other patients.

10 Who is organising and funding this study?

Researchers at the University of Bristol are running this study. The study is being undertaken as part of an academic degree (PhD). The work is supported by the Medical Research Council (MRC) Network of Hubs for Trials Methodology Research and the National Institute for Health Research Bristol Biomedical Research Centre (NIHR BRC

Bristol). The study has NHS ethical approval from West Midlands – Coventry & Warwickshire Research Ethics Committee.

11 What if something goes wrong?

If you have any concerns or questions about this study please contact us on 0117 928 7367. For independent advice or to make a complaint, you can contact *[insert local address/telephone/email for University Hospitals Bristol NHS Foundation Trust Patient Support and Complaints Team, or North Bristol NHS Trust Advice & Complaints Team]*

Thank you for taking the time to read this information.

Further information about the use of your personal information collected as part of this research study

The University of Bristol is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Bristol will keep identifiable information about you for three years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

NHS will collect information from you and your medical records for this research study in accordance with our instructions. NHS will use your name, NHS number and contact details to make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from the University of Bristol and regulatory organisations may look at your medical and research records to check the accuracy of the research study. NHS will pass these details to the University of Bristol along with the information collected from you and your medical records. The only people in the University of Bristol who will have access to information that identifies you will be people who need to contact you to send you the study survey, collect follow up information for the study, or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

This information is provided to fulfil the transparency requirements under the General Data Protection Regulation (GDPR) for health and social care research. Please contact the study researcher if you have any further questions.
Rhiannon Macefield Tel: 0117 928 7367 Email: r.macefield@bristol.ac.uk

Appendix 32. Wound photography instructions for Selfi wound study participants

University of BRISTOL

The Selfi wound study

Self-taken **i**mages of surgical wounds

Exploring the feasibility of a method for the collection of self/carer-taken images of primary surgical wounds after leaving hospital

- Thank you for agreeing to take part in this study, which is exploring whether it is possible for people to take a clear photograph of their wound after they have left hospital using their own digital camera.
- We would like you to take a photograph of your surgical wound(s). To help you take a clear photograph, please follow the instructions provided on the next page as well as you can.
- **Within the next few days you will receive an email from the study team with details on how to electronically 'upload' your photos and send them in to the study team**. Please keep a look out for this email.
- Ideally, please use the camera on your **mobile phone** or another mobile digital device like an **iPad® or tablet** computer to take the photograph. It will need to be a device that you can directly use to access the internet, or a device that you can easily transfer your photograph to your computer from after taking it.
- **Another person can help** take the photograph for you, for example if your wound is in an awkward place to photograph yourself, or if you need help for any other reason. You could also use a prop such as a selfie stick.
- If you have **more than one wound**, please take a separate photograph of each one if you can.
- If your wound is covered with a dressing, take the photograph **when the dressing is due to be changed** if possible.
- A sticker (20mm scale ruler) should be provided along with these instructions for you to include in the photograph.

How to contact the study team

If you have any questions about this study or how to take your photographs, please talk to the study researcher:

Ms Rhiannon Macefield
Tel: 0117 928 7367 Email: r.macefield@bristol.ac.uk
Bristol Medical School, University of Bristol, Canynge Hall, 39 Whatley Road, Bristol. BS8 2PS.

Please turn over...

Preparation for taking a photograph of your wound

1. Please **wash your hands** with soap and water before and after taking the photos.
2. Please take the photo in a place with **good light**; if possible open any curtains or blinds (keeping your privacy protected as much as you wish) or turn on a light.
3. If you have a wound **dressing or plaster**, carefully peel it away or take it off so that the wound is visible. **Do not do anything to clean the wound** that you have not been advised to do by your doctor or nurse.
4. Remove any **clothing** from around the wound **so that it will not show in the photo** but please cover up any parts of your body you would prefer not to be seen (for your own privacy and dignity). If possible, please also cover up anything on your body near your wound that would make you identifiable, such as a tattoo, birthmark, other scars or piercings.
5. Stick the provided **scale ruler** somewhere near to your wound so that it will be seen in the photo.
6. If you think some **background** will show in your photo (for example the chair or bed underneath you), please try to make sure it is **plain** rather than patterned so that it does not affect the colour contrast of the photograph. White or a pale colour is best.
7. If possible, please turn on the flash  on the camera.

Instructions for taking a photograph of your wound

8. Find a **comfortable position** to take your photo. You can **sit, lie down or stand**.
9. Ideally, take a **clear, close-up photograph of the wound** so it can be assessed for how it is healing. Hold the camera at a distance so that you can photograph the **whole wound** if possible. If your wound is long, you may need to take more than one photo to capture the whole wound.
10. **Point the camera directly at the wound** (i.e. straight in front of the wound and not at an angle) if possible. It may be easier to use the front-facing camera on your device (selfie mode). You should be able to do this by pressing a button on your device that looks something like the picture shown here.

11. Allow the camera to **focus** on its own (auto-focus) or focus the camera manually. This can usually be done by tapping the screen or pressing down the button slightly. You may need to move the camera further away if it cannot focus.
12. **Check** your photo(s) on the camera display screen. It should be **in focus, not blurry, well-lit** and **with no shadows** over the wound if possible. You can try taking a picture with and without the flash (if available) to see what looks best. It is very important that the photo does not show your face. If you need to, take another photo until you are happy that you have the clearest photo possible.
13. It is recommended to delete photos that are no good as you go along so you are only left with the ones that you want. This will make things easier when you come to uploading them to the electronic system to send in to the study team.
14. If your wound was covered with a dressing, re-cover it (preferably with a new dressing) after taking the photograph.

Thank you for following these instructions.

Appendix 33. Debriefing questions included in the Selfi wound study online survey (Study 2; Phase 2)

Approximately how long did it take to take the wound photograph(s)?

1, less than 5 minutes
2, 5 to 10 minutes
3, 10 to 15 minutes
4, more than 15 minutes

Who took the photograph(s)?

1, I took them myself
2, Someone else took them
3, I took some and someone else took others

Who helped to take the photographs?

1, family member
2, nurse or other healthcare professional
3, friend or neighbour
9, other person

Was any help needed from another person to upload the photograph?

Yes/No

Who helped to upload the photograph(s)?

1, family member
2, nurse or other healthcare professional
3, friend or neighbour
9, other person

How would you rate your level of experience with using your mobile device?

0, Not experienced
1, Somewhat experienced
2, Moderately experienced
3, Very experienced
4, Expert

On average, how often do you send or receive emails using your phone or tablet?

0, Never
1, Yearly
2, Monthly
3, Weekly
4, Every day

On average, how often do you take photographs using your phone or tablet?

0, Never
1, Yearly
2, Monthly
3, Weekly
4, Every day

Appendix 34. Prompt sheet for Selfi wound study participant follow-up calls (Study 2; Phase 2)

1. How easy was it to follow the instructions to take a photograph of your wound?
2. Did you need help any with taking the photograph(s)? If so, which part(s) did you need help with and why?
3. Were there any parts of the instructions that you found confusing or difficult to follow? If so, which part(s) did you need help with and why?
4. How long did it take to take the photograph(s)?
5. How easy was it to access the study online database / webpage?
6. How easy was it to upload you wound photograph?
7. Did you need help with logging into the system and/or uploading the photograph(s)?
8. How long did it take to upload the photograph(s) and fill out the questions online?
9. Do you have any comments on the design of the study online system?
10. Do you have any other comments or feedback you can give us about the overall process of taking and uploading your wound photograph(s)?